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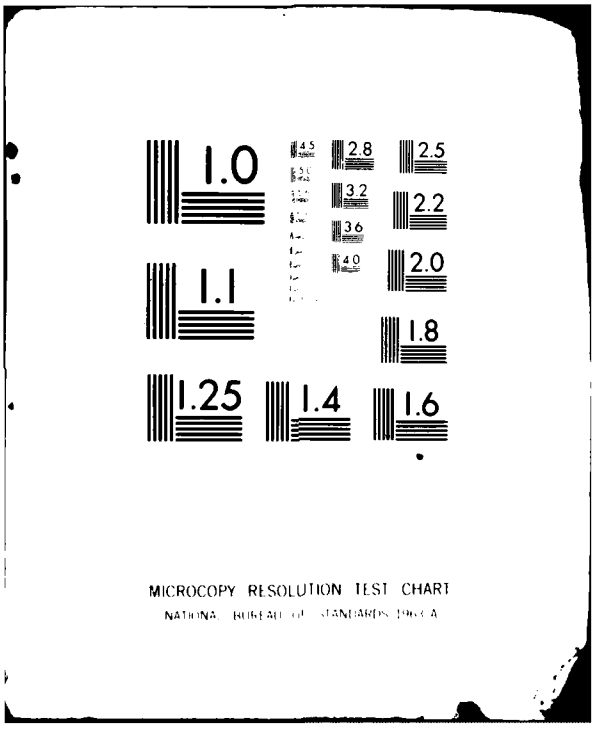
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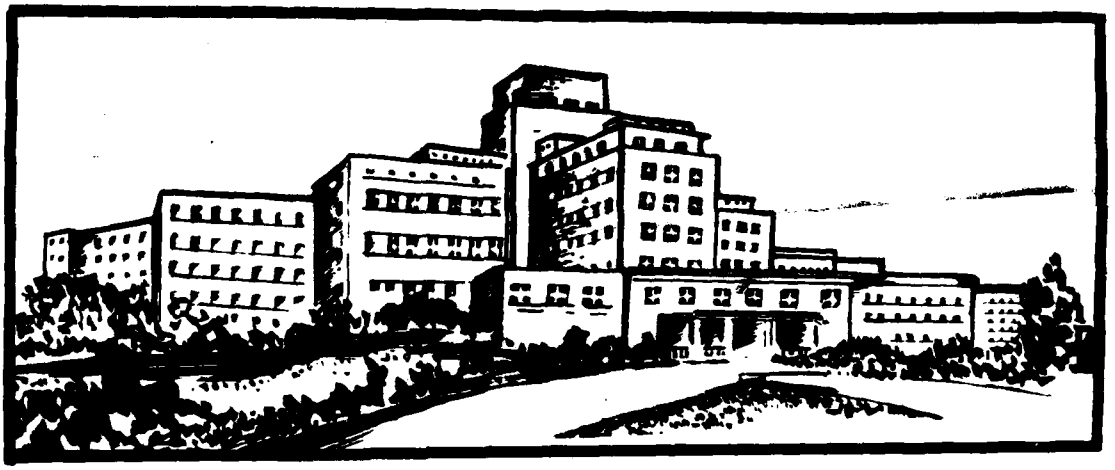

CLINICAL INVESTIGATION PROGRAM

REPORT CONTROL SYMBOL MED-300

FISCAL YEAR 1981

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SECURITY CLASSIFICATION OF THIS PAGE (When Data Entered)

REPORT DOCUMENTATION PAGE	READ INSTRUCTIONS BEFORE COMPLETING FORM
1. REPORT NUMBER: MED-300	2. GOVT ACCESSION NO: AD-A110 734
3. RECIPIENT'S CATALOG NUMBER	
4. TITLE (and Subtitle): CLINICAL INVESTIGATION PROGRAM Annual Progress Report	5. TYPE OF REPORT & PERIOD COVERED: ANNUAL - FY 81
6. PERFORMING ORG. REPORT NUMBER	
7. AUTHOR(s): SAMUEL A. CUCINELL, M.D., COL, MC Chief, Department of Clinical Investigation	8. CONTRACT OR GRANT NUMBER(s)
9. PERFORMING ORGANIZATION NAME AND ADDRESS: Department of Clinical Investigation Tripler Army Medical Center Tripler AMC, Hawaii 96859	10. PROGRAM ELEMENT, PROJECT, TASK AREA & WORK UNIT NUMBERS
11. CONTROLLING OFFICE NAME AND ADDRESS: Commander HQ, Tripler Army Medical Center Tripler AMC, Hawaii 96859	12. REPORT DATE: 1 October 1981
	13. NUMBER OF PAGES
14. MONITORING AGENCY NAME & ADDRESS (if different from Controlling Office): Office of The Surgeon General Department of The Army Washington, D.C. 20314	15. SECURITY CLASS. (of this report): UNCLASSIFIED
	15a. DECLASSIFICATION DOWNGRADING SCHEDULE

16. DISTRIBUTION STATEMENT (of this Report)

APPROVED FOR PUBLIC RELEASE: DISTRIBUTION UNLIMITED

17. DISTRIBUTION STATEMENT (of the abstract entered in Block 20, if different from Report)

18. SUPPLEMENTARY NOTES

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19. KEY WORDS (Continue on reverse side if necessary and identify by block number)

Clinical investigations; experimental projects; research protocols; in-house research; publications, presentations of research data; protocol status; experimental design.

20. ABSTRACT (Continue on reverse side if necessary and identify by block number)

Subject report identifies those individuals who are conducting investigative protocols at Tripler Army Medical Center. An abstract of each protocol giving abbreviated technical objectives, methods, and progress is presented.

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ANNUAL PROGRESS REPORT

CLINICAL INVESTIGATION PROGRAM
Reports Control Symbol MED-300

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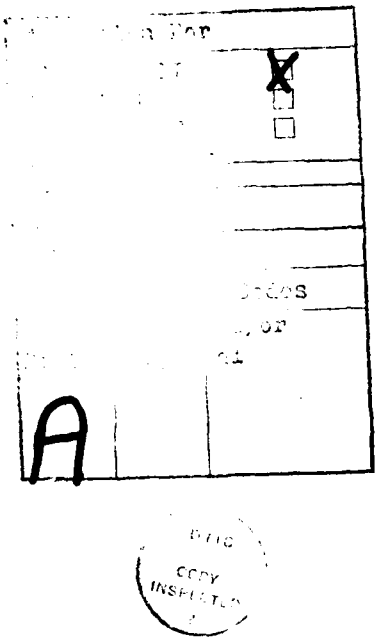


DEPARTMENT OF CLINICAL INVESTIGATION
TRIPLER ARMY MEDICAL CENTER
Tripler AMC, Hawaii 96859

FOREWORD

Contained herein are progress reports on research projects fostered by the Clinical Investigation Program at Tripler Army Medical Center (TAMC) during Fiscal Year 1981.

The Clinical Investigation and Human Use Committees reviewed all proposals for their scientific merit, medical applicability, and risk to human subjects. In conducting the research described in this report, the investigators adhered to the "Guide for Laboratory Animal Facilities and Care" as promulgated by the National Academy of Sciences/National Research Council, the criteria established by the American Association for Accreditation of Laboratory Animal Care, and the principles embodied in the Declaration of Helsinki.

This Annual Progress Report contains publications, presentations, awards, proposals, preliminary findings, unit staffing, and fiscal data.

SAMUEL A. CUCINELL, M.D.
Colonel, MC
Chief, Dept of Clinical Investigation

DEPARTMENT OF CLINICAL INVESTIGATION
TRIPLER ARMY MEDICAL CENTER

UNIT SUMMARY

A. OBJECTIVES: Previous to the provisions of 1981, the duty of the Department of Clinical Investigation (DCI) was the provision of support for medical research by the TAMC staff. Now DCI is responsible for the quality and administrative monitoring of the research as well. Emphasis on quality has required additional reviews and preparation of protocols; possibly this relates to the decrease in protocols. Unfortunately, zero of seven protocols submitted to the Human Subjects Research Review Board (HSRRB) this year have been approved in time for the work to be carried out, reflecting the increased demand for quality.

B. TECHNICAL APPROACH: All research, investigations, and training activities within the Department of Clinical Investigation are conducted under the guidance of AR 40-7, AR 40-38, AR 70-25, AR 70-18, and HSC Regulation 40-23. Careful monitoring of all approved protocols is conducted in order to assure strict compliance with the applicable regulations.

C. STAFFING:

Name	Rank	MOS	Title
Cucinell, Samuel A.	COL	61F00	Chief
Hadick, Clayton L.	CPT	64A00	C, Veterinary Svc
		68C00	Biochemist
Dotson, Carroll R.	CPT	68A00	C, Microbiology Svc
Coussens, Wayne R.	CPT	68T00	Research Psychologist
Pulu, Tavake	SFC	92B40	NCOIC
Lewis, Clifford D.	SP5	01H20	Biomed Science NCO
Fallaria, Nonilon A	SP5	01H20	Biomed Science NCO
Davis, Cynthia R.	SP5	91T20	Animal Sp
Smart, Thomas P.	SP5	91T20	Animal Sp
Sanders, Teresa C.	SP4	91T10	Animal Sp
Ashburn, Cynthia J.	PFC	92B10	Med Lab Sp
Claybaugh, John R.	GS14	00413	C, Physiology Svc
Bryant, Gordon H.	GS11	00802	Biomedical Engineer
Palmer, Carolyn A.	GS09	00404	Biological Lab Tech
Sato, Aileen K.	GS09	00404	Biological Lab Tech
Hashiro, Glenn M.	GS07	00403	Microbiologist
Cornette, Kuuleialoha	GS07	00413	Career Intern Physiologist
Masunaga, Lois E.	GS06	01087	Editorial Assistant
Yamamoto, Cynthia T.	GS04	00312	Clerk-Steno
Lacal, Ernie A.	WG02	03566	Custodial Worker

D. FUNDING:

Type	Preceding Year	Current Year
Civilian personnel to include benefits	$151,461.22	$167,320.45
Consumable supplies	78,986.15	65,782.90
Civilian contracts to include consultants	3,047.30	1,694.20
TDY	16,180.58	16,877.22
Publications	1,622.86	1,899.77
Noninvestment equipment (Minor MEDCASE)	651.40	1,447.85
Other OMA Trans & Taxes	409.21	212.99
Other OMA Maint. & Rentals	7,586.80	1,509.99
OMA Total	259,945.52	256,745.37
MEDCASE	41,370.41	85,594.00
Other		
Military	220,998.58	247,946.16
TOTAL	$522,314.51	$589,864.65

E. PROGRESS: 97 projects are reported, of which 23 have been terminated, 17 completed, and 57 ongoing. There have been 31 publications, 15 resulting from research projects, and 23 presentations at national and regional scientific meetings, 13 resulting from research projects. The detail sheets should be examined for specific information on the individual projects.

The number of publications has climbed steadily since the start of the DCI at TAMC in 1971. As a baseline from 1968 to 1970, there were nine publications per year. From 1971 to 1980 the average was 17.4 ± 5.9 per year. Even before DCI had any facilities at all in 1971, there was a sharp increase. This suggests that simply the idea of research encouraged by the command is valuable in stimulating effort (Fig. 1). Since 1979, DCI has taken responsibility for preparation of manuscripts throughout TAMC. The number of manuscripts prepared by DCI has increased during these past three years compared to the previous five years for which data is available. The number of publications prepared includes major rewrites. On the other hand, the number of manuscripts submitted for publication clearance has remained constant. This manuscript preparation service is believed to

be the single most important thing in increasing the publication rate, not any dramatic increase in research, money, or personnel.

If the measure of success is publication, then DCI does well. The following table compares the past three years. There has been an increase in the number of publications resulting from protocols. What is disturbing is that the same authors' names are repeated over again. These publications do not represent a cross-section of the hospital, but rather the efforts of a limited number of individuals. Considering the number of protocols which are not published each year, it is possible for TAMC to have 50 manuscripts per year output. Numbers of publications do not necessarily reflect quality of work or completion of the mission. But what other measure is there?

	No. of Publications	No. of Publications from Protocols	No. of DCI Publications
1979	14	2	1
1980	23	4	3
1981	31	15	9

F. PROBLEMS: The main problems are delay and lack of interest, time, and money. During the past two years, 8 months have been required on the average for resolution of a protocol submitted to the HSRRB. Six months is the shortest interval, and one year to final approval has occurred. The delay involves the consultant reviewers to the HSRRB who always find imperfections in the protocols. The resolution of this problem is to prepare perfect protocols.

The number of protocols reported this year has decreased from 88 to 73 (noncancer) protocols. The total protocols submitted to the Clinical Investigation Committee were 38 in 1980 and 17 in 1981. Articles have been written on the decrease in physician research. There is no reason to suspect that military physicians should be any more research-minded than civilians. Although the reason for the decrease in the civilian sector is said to be an increased interest in primary care and increased debts from medical school, TAMC's problem is the limitation on time of the physician staff. This is compounded by the aging equipment in DCI. The x-ray equipment, sterilizers, anesthesia machines, and surgical tools are 10 years old. Since research is the new and the advanced, our equipment simply is not adequate to meet the demands of modern surgical technique and postoperative care. The veterinary section is struggling to maintain a basic animal colony, and major surgery and postoperative care are marginal. As the surgical procedures decrease, the veterinary personnel become less experienced.

A chronic problem continues to be that protocols have been completed and reached the preliminary publication stage when they are

abandoned because of PCS of the investigator. Previously, one-half of all completed protocols were left unpublished. This has been reduced to one-quarter.

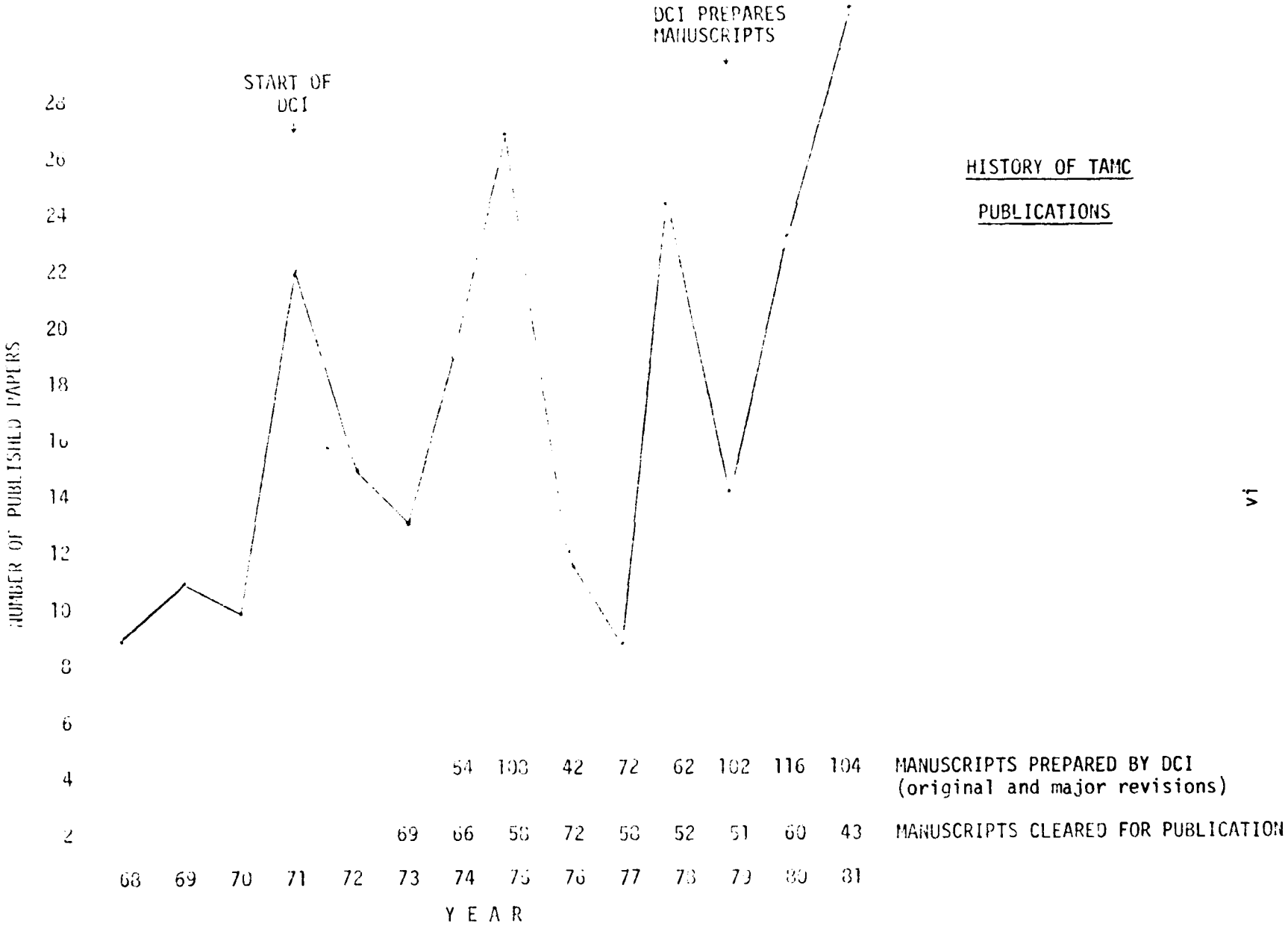
During the past year we lost our full AAALAC accreditation. The HSC Inspector General's inspection team found the DCI deficient in the animal colony as well. Remarkable effort has been made to correct the deficiencies and accreditation is expected to be reinstated.

RESOLUTION OF PROBLEMS: A short-term solution of the problems of physician time and improvement of the quality of protocols is the preparation of protocols by more senior staff physicians with longer tours at TAMC, and the incorporation of the house staff into ongoing established programs. This is the classical mentor system. It may discourage novel efforts by the house staff but novel efforts by house staff have not really succeeded.

The quality of the surgical support in DCI must be improved to make experimental surgery successful. This involves improving the maintenance of our equipment and improving our MEDCASE. Although we have been awarded $85,000 in MEDCASE funds in FY 81, not one item from these funds has arrived in Hawaii as of the submission of this report. MEDCASE support must be found to replace the X-ray system, since the radiologists cannot be expected to do advanced procedures with equipment from the 1960's.

The DCI of TAMC is ten years old. It has continued to have the support of an involved commander, MG Edward Huyke, and our former HSC program director, COL Norman Beam.

The DCI is reorienting its administrative and research programs to meet new requirements.


DCI PREPARES MANUSCRIPTS
START OF DCI
HISTORY OF TAMC
PUBLICATIONS
NUMBER OF PUBLISHED PAPERS
28
26
24
22
20
18
16
14
12
10
8
6
4
2
54 108 42 72 62 102 116 104
MANUSCRIPTS PREPARED BY DCI
(original and major revisions)
69 66 58 72 58 52 51 60 43
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YEAR

Figure 1

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Code: C - Completed; O - Ongoing; T - Terminated; P - Published; PR - Presented; SP - Submitted for Publication

PUBLICATIONS

DEPARTMENT OF CLINICAL INVESTIGATION

Bryant, G. H., Cucinell, S. A., and Goodwin, B. S.: Measurement of Hepatic Venous Blood Flow in Shock by Thermal Dilution. Proc West Pharmacol Soc 24: 23-25, 1981. (C)

Dressendorfer, R. H., Wade, C. E., and Amsterdam, E. A.: Development of Pseudoanemia in Marathon Runners During a 20-Day Road Race. JAMA 246(11): 1215-1217, Sep 81. (C)

Dressendorfer, R. H., Wade, C. E., Hornick, C., and Timmis, C. C.: High-Density-Lipoprotein Cholesterol, Alcohol Intake, and Liver Function in Marathon Runners During a Twenty-Day Road Race. New Engl J Med, Sep 1981. (C)

Mercado-Simmen, R., Goodwin, B., Ueno, M., Yamamoto, S., Bryant- Greenwood, G.: Rat Receptor in the Myometrium and Cervix of the Pig. Biol Reprod, in press. (C)

O'Brien, J. C.: Tyrosine Aminotransferase Sensitivity to Bromodeoxyuridine During Restricted Intervals of S Phase in Hepatoma Cells. J Cell Biol 84: 629-632, Dec 1980. (C)

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Wade, C. E. and Claybaugh, J. R.: Plasma Renin Activity, Vasopressin Concentration, and Urinary Excretory Responses to Exercise in Men. J Appl Physiol 49(6): 930-936, Dec 1980. (C)

Wade, C. E., Dressendorfer, R. H., O'Brien, J. C., and Claybaugh, J. R.: Renal Function, Aldosterone, and Vasopressin Excretion Following Repeated Long-Distance Running. J Appl Physiol 50(4): 709-712, 1981. (C)

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Long, W. H., Rudd, E. G., and Dillon, M. B.: Intrauterine Irrigation with Cefamandole Nafate Solution at Cesarean Section: A Preliminary Report. Am J Obstet Gynecol 138(7): 755-758, Dec 1980. (C)

DEPARTMENT OF PEDIATRICS

Enzenauer, R. W., Hastings, C. P.: Leukemia and Absent Pectoralis Major: No Association? Am J Dis Child 135: 763-765, Aug 1981.

DEPARTMENT OF PSYCHIATRY

Rock, N. L., Shearer, R. D., Skogberg, P. K.: Therapeutic Dosage and Window with Trifluoperazine in Childhood Psychosis (Autism). J Psychiatr Treatment Eval 2: 241-244, 1980. (C)

DEPARTMENT OF RADIOLOGY

Dean, B. and Chacko, A.: In-111 DTPA Detection of Cerebrospinal Fluid Leakage from the Thoracic Spine. J Nucl Med 22(5), May 1981. (C)

Hanson, J. V.: A Simple Method for Drying the Umbilical Stump. Family Physician, Dec 1980.

Johnson, J. F.: Oropharyngeal Choristoma in a Newborn. Br J Radiol 53(634): 1007-1009, Oct 1980.

Johnson J. F. and Cronk, R. L.: The Pseudotransition Zone in Long Segment Hirschsprung's Disease. Pediatr Radiol 10: 87-89, 1980.

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DEPARTMENT OF SURGERY

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Blight, E. M.: Traumatic Renal Hemorrhage Exacerbated by Heparin. J Trauma 20(11): 989-991, Nov 1980.

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Reyna, T. M. and Maudauss, W. C.: Emergency Treatment of Epidural Hematoma: Case Report. Milit Med 146(7): 504-506, Jul 1981.

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Smith, S. B. and Major, J. E.: Operations for Morbid Obesity: Is There a Place for Them in Military Hospitals? Milit Med 146(2), Feb 1981.

Weddel, S. J. and Ritter, R. R.: Serum Levels Following Epidural Administration of Morphine and Correlation with Relief of Postsurgical Pain. Anesthesiology 54: 210-214, Mar 1981.

PRESENTATIONS

DEPARTMENT OF CLINICAL INVESTIGATION

Brooks, D. P. and Claybaugh, J. R.: Reduced Mean Arterial Blood Pressure (MABP) and Plasma ADH After Aldosterone Infusion into Dehydrated Conscious Dogs. 31st Annual Fall Meeting, American Physiological Society, Toronto, Canada, Oct 1980. (C)

Bryant, C. H.: Hepatic Venous Blood Flow in Shock by Thermal Dilution Technique. 65th Annual Meeting, Federation of American Societies for Experimental Biology, Atlanta, GA, Apr 19[illegible] (C)

Claybaugh, J. R.: Urinary Metabolites of [illegible]vpressin: Consequences in Radioimmunoassay. 31st Annual Fall M[illegible] American Physiological Society, Toronto, Canada, Oct 1980. (C)

Claybaugh, J. R.: Lack of Effect of Acetazolamide on Increase in ADH During First 24 Hrs at 13,600 Ft in Man. 65th Annual Meeting, Federation of American Societies for Experimental Biology, Atlanta, GA, Apr 1981. (C)

Cucinell, S. A.: Chemical Agent Casualties. 38th Parallel Medical Society Meeting, Yongsan Military Reservation, Seoul, Korea, Apr 1981.

Dotson, C. R.: Comparison of Antibiotic Susceptibility Patterns and Bacteriophage Types of Coagulase-Positive Staphylococci Isolated from Newborn Skin. Annual Meeting, American Microbiological Society, Dallas, TX, Feb 1981. (C)

Goodwin, B. S., Jr.: Hepatic Blood Flow Measurement and Blood Sampling Techniques in the Dog. 31st Annual Session, American Association for Laboratory Animal Science, Indianapolis, IN, Oct 1980. (C)

Hadick, C. L.: Intraocular Prosthesis in a Cynomolgous Monkey (Macaca Fascicularis). 32nd Annual Session, American Association for Laboratory Animal Science, Salt Lake City, Utah, Sep 1981.

O'Brien, J. C., Jr.: Endotoxin Effects on Rat Hepatocytes in Monolayer Culture. 65th Annual Meeting, Federation of American Societies for Experimental Biology, Atlanta, GA, Apr 1981. (C)

DEPARTMENT OF OBSTETRICS AND GYNECOLOGY

Rudd, E. G.: Intrauterine Irrigation with Cefamandole Nafate Solution at Cesarean Section. Armed Forces OB-GYN Seminar, Orlando, FL, Oct 1980. (C)

DEPARTMENT OF PEDIATRICS

Suttle, D. L.: Sports Medicine for the Non-orthopedist. 24th Annual Postgraduate Course, University of Southern California School of Medicine, Aug 1981.

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Newell, J. D.: Computerized Tomographic (CT) Appearance of the Myocardium After Reversible and Irreversible Ischemic Injury. 29th Annual Meeting of the Association of University Radiologists, Apr 1981.

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Andersen, C. A.: Evaluation and Treatment of Common Venous Disorders. 38th Parallel Medical Society Meeting, Yongsan Military Reservation, Seoul, Korea, Apr 1981.

Greenfield, G. Q., Jr.: Low Back Pain in Outpatients. Annual Meeting, Society of Military Orthopedic Surgeons, San Antonio, TX, Nov 1980. (C)

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Lopez, A. G., Jr.: Case Report of Extranasal Glioma, Intracranial Extension. Annual Meeting, American Academy of Otolargyngology, Head and Neck Surgery, New Orleans, LA, Sep 1981.

Rainey, R. K.: Compartment Syndrome. Annual Seminar, American College of General Practitioners, Ohio Chapter, Dellroy, OH, Aug 1981. (C)

Reddick, E. J.: Preparation of Burn Patients for Aeromedical Evacuation. 38th Parallel Medical Society Meeting, Yongsan Military Reservation, Seoul, Korea, Apr 1981.

Reinker, K. A.: Patterns of Progression in Legg-Perthes Disease. 44th Annual Meeting, Western Orthopedic Association, Kauai, HI, Oct 1980.

Soderdahl, D. W.: Prediction of Fertility After Varicocele Correction by the Zona-Free Hamster Ova Technique. Annual Meeting, American Urological Association, Boston, MA, May 1981. (C)

Weddel, S. J.: Epidural Morphine: Serum Levels and Relief of Postsurgical Pain. ASA Meeting, St. Louis, MO, Oct 1980.

Detail Summary Sheet

Date: 8 Jan 82	Prot No: 138/75	Status: Ongoing
TITLE: Evaluation of the Cardioesophageal Sphincter Competence by Comparison of Intraluminal Esophageal Sphincter and Gastric Pressure with Thoracic, Hiatal, and Abdominal Pressure		
Start Date: Sep 74		Est Comp Date: Sep 83
Principal Investigator: Gordon H. Bryant		Facility: Tripler Army Medical Center
Dept/Sec: Dept of Clinical Investigation		Associate Investigators: Tom R. De Meester, M.D.
Key Words: Cardioesophageal sphincter		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $3300.	Periodic Review Results: Continue

OBJECTIVES: To obtain comparative gastric and cardioesophageal sphincter pressures during 24-hour pH testing for nocturnal reflux.

TECHNICAL APPROACH: For more exact analysis of causative factors of nocturnal reflux and its surgical correction, the direct measurement of gastric and cardioesophageal pressures are to be made simultaneously with pH in 24-hour studies. Reduction of errors due to perfused side-hole catheter pressure measurements in the cardioesophageal sphincter are to be made by utilizing a three-channel, semiconductor, gastro-esophageal probe presently available. This device is to be modified so as to incorporate both a Dent sleeve system in the center section and a pH probe.

PROGRESS: The Dent sleeve catheter has not proved to be of advantage in 24-hour pH/esophageal pressure studies. In common with all water perfused side-hold catheter systems for intraesophageal pressure measurement, hydrostatic artifacts due to patient movement introduce uncertainties in recording interpretation. An additional research study for fabrication of a nonperfused catheter system is being instituted so as to eliminate this problem. Nonavailability of a suitable catheter system for these measurements has necessitated the suspension of this project for six months.

DeMeester, TR, Wernly, JA, Bryant, GH, Little, AG, Skinner, DB: Clinical and In Vitro Analysis of Determinants of Gastroesophageal Competence: A Study of the Principles of Antireflux Surgery. Am J Surg 137:39-45, Jan 1979.

Wernly, JA, DeMeester, TR, Bryant, GH, Wang, C-I, Smith, RB and Skinner, DB: Intra-Abdominal Pressure and Manometric Data of the Distal Esophageal Sphincter. Arch Surg 115:534-539, April 1980.

Detail Summary Sheet

Date: 5 Jan 82 Prot No: 34/79 Status: Ongoing

TITLE: Fabrication of a Catheter for the Determination of Liver Blood Flow in Dog and Man

Start Date: Oct 79		Est Comp Date: Sep 82
Principal Investigator: Gordon H. Bryant		Facility: Tripler Army Medical Center
Dept/Sec: Dept of Clinical Investigation		Associate Investigators: COL Samuel A. Cucinell, MC CPT Clayton L. Hadick, VC
Key Words: Liver blood flow		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $2500.	Periodic Review Results: Continue

OBJECTIVES: Development of a thermodilution catheter which will easily and repeatedly give an accurate measure of hepatic vein blood flow in larger animals.

TECHNICAL APPROACH: Technique for fabrication of catheters for blood flow measurement is now a routine procedure in the Department of Clinical Investigation at TAMC. Results to date have demonstrated a degree of variability, particularly in the case of small flows, i.e., less than 250 ml/minute. Cause and cure of such deficiencies have therefore been undertaken using an in vitro model of the IVC.

PROGRESS: It has been found, using a more carefully designed in vitro model, that factors such as distance between thermistor and injection site, volume and velocity of injectate, and geometry of injection system all have considerable influence on accuracy of flow measurement. Reasons for these phenomena and their elucidation should lead to the desired improvement in accuracy of results in the near future.

Hepatic Blood Flow Measurement and Blood Sampling Techniques in the Dog. Presented at the 31st Annual Session of the American Association for Laboratory Animal Science, Indianapolis, IN, October 1980.

Hepatic Venous Blood Flow in Shock by Thermal Dilution Technique. Presented at the Annual Meeting of the Federation of American Societies for Experimental Biology, Atlanta, GA, April 1981.

Bryant, G. H., Cucinell, S. A., Goodwin, B. S.: Measurement of Hepatic Venous Blood Flow in Shock by Thermal Dilution. Proc West Pharmacol Soc 24:23-25, 1981.

Detail Summary Sheet

Date: 11 Jan 82	Prot No: 5/81	Status: Ongoing

TITLE: Fabrication of a Nonperfused Gastric Motility Catheter

Start Date:	Est Comp Date:
Principal Investigator: Gordon H. Bryant	Facility: Tripler Army Medical Center
Dept/Sec: Dept of Clinical Investigation	Associate Investigators:
Key Words: Gastric motility catheter	

Accumulative FEDCASE Cost:	Est Accumulative OMA Cost:$300.	Periodic Review Results: Continue

OBJECTIVE: To make possible simultaneous distal esophageal sphincter (DES) pressure monitoring with 24-hour pH studies in patients suffering from nocturnal gastric reflux.

TECHNICAL APPROACH: Proposal is to utilize piezo electric or thermistor techniques for pressure measurement within the DES and flaccid, water-filled balloons connected to conventional pressure transducers for gastric and esophageal pressure. Small barium titanate strips with central pivot point can be used in conjunction with field effect thermistors for required pressure measurements within the DES. Alternatively, paired spaced thermistors could be used where one unit acts as a heat source and the other a heat unit. Esophageal "squeeze" would vary the separating distance between the two thermistors in this case.

PROGRESS: Problems of time limitation, location and availability of suitable materials have stultified progress in this study. It has accordingly been suspended until other work of higher priority is completed.

Detail Summary Sheet

Date: 14 Jan 82	Prot No: 38/76	Status: Ongoing

TITLE: Further Studies on the Site of Action of Circulating Angiotensin II on Plasma ADH Concentration

Start Date: Jul 76	Est Comp Date: Sep 83
Principal Investigator: John R. Claybaugh, Ph.D.	Facility: Tripler Army Medical Center
Dept/Sec: Clinical Investigation/Physiology	Associate Investigators: CPT Clayton L. Hadick, VC
Key Words: Angiotensin Antidiuretic hormone Dog	

Accumulative MEDCASE Cost:	Est Accumulative CMA Cost: $3000.	Periodic Review Results: Continue

OBJECTIVES: To determine if angiotensin II augments osmotic stimulation of ADH mediated via hepatic osmoreceptors.

TECHNICAL APPROACH: Following a report in which hepatic osmoreceptor control of vasopressin release was suggested, we conducted two pilot experiments in an attempt to verify the existence of hepatic osmoreceptor vasopressin control, and secondly, whether these osmoreceptors are also augmented by angiotensin II as are the central osmoreceptors. Chronic indwelling cannulae were surgically placed in the portal vein via the splenic vein. There were two ports allowing upstream infusion of hypertonic solutions, and downstream sampling for osmolality determinations. After the cannula was put in place the dogs were allowed to recover and subsequently used for experiments in the conscious state. Our intention was to conduct at least three experimental runs on each dog, one comparing peripheral venous hypertonic NaCl vs portal venous infusions, another comparing portal venous infusions of hypertonic NaCl with and without simultaneous infusions of angiotensin via a peripheral vein, and third peripheral intravenous infusions of hypertonic NaCl with angiotensin infused either peripherally or via the portal vein.

PROGRESS: Preliminary experiments (2) suggest the existence of hepatic osmoreceptor stimulation of vasopressin and also suggest the possibility of angiotensin II augmentation of the response, but continuation of the experiment has been delayed due to changes in veterinary officers and subsequent delays imposed by manpower shortages.

Detail Summary Sheet

Date: 7 Jan 82 Prot No: 9/77 Status: Ongoing
TITLE: The Effect of Sodium Balance on the Vasopressin Response to Blood Volume Reduction

Start Date: Sep 76	Est Comp Date: Sep 82
Principal Investigator: John R. Claybaugh, Ph.D.	Facility: Tripler Army Medical Center
Dept/Sec: Clinical Investigation/Physiology	Associate Investigators: CPT Clayton L. Hadick, VC COL Peter J. Barcia, MC
Key Words: Conscious dogs Blood volume reduction Sodium balance	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $1800.
Periodic Review Results: Continue	

OBJECTIVES: To determine whether negative sodium balance increases the vasopressin response to hemorrhage.

TECHNICAL APPROACH: Conscious dogs will be hemorrhaged 10% of the estimated blood volume after two weeks of low, normal, or high sodium intakes. Blood samples will be obtained prior to and five minutes after hemorrhage, and one hour after the return of hemorrhaged blood. Six dogs will be prepared with exteriorized carotid loops and with chronic indwelling left atrial cannulae. The dogs will be hemorrhaged at a rate of 0.4 ml/kg/min with blood samples taken at time 0, 10, 20, and 30 minutes, corresponding to 5, 10, and 15 percent hemorrhages. This regimen will be conducted four times on different sodium diets.

PROGRESS: To date we have shown that low sodium diet enhances the ADH response to equal volume hemorrhages in the same animal. This occurs despite similar initial values of plasma ADH concentration in the two states. Research by other laboratories has demonstrated a possible change in sensitivity of baroreceptor control of renin release, which may also be influencing the ADH response in a similar fashion. Inhibition of the renin-angiotensin system does not alter the ADH response to hemorrhage significantly; however, we would like to investigate this point a little further before final publication. In addition, the sensitivity of baroreceptor stimulation of ADH release in different sodium balances should be further investigated.

Claybaugh, J.R., Wade, C.E., Goodwin, B.S., and Barcia, P.J. ADH, renin, and cardiovascular responses to slow continuous hemorrhage in conscious dogs on low Na diet with inhibition of converting enzyme. Fed. Proc., 38:967, Abstract 3890, 1979.

Detail Summary Sheet

Date: 5 Jan 80	Prot No: 11/77	Status: Ongoing

TITLE: Enzyme Immunoassay of Arginine Vasopressin

Start Date: Apr 77		Est Comp Date: Apr 85
Principal Investigator: John R. Claybaugh, Ph.D.		Facility: Tripler Army Medical Center
Dept/Sec: Clinical Investigation/Physiology		Associate Investigators:
Key Words: Enzyme immunoassay		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $2500.	Periodic Review Results: Continue

OBJECTIVES: (a) To develop the technology for and assess the clinical and research efficacy of enzyme immunoassay methods for arginine vasopressin (AV) measurements in biological fluids in comparison with standard radioimmunoassays; and (b) to partially automate enzyme immunoassay techniques to allow for greater productivity in hormone measurement by routine laboratory personnel.

TECHNICAL APPROACH: This study consists of two phases: (1) the validation of enzyme immunoassay for AV using hormone coupled B-galactosidase, comparing results to currently available radioimmunoassays; and (2) partial automation of the enzyme immunoassay for B-galactosidase.

PROGRESS: Preliminary experiments were initiated in developing the enzyme assay for B-galactosidase. Work stopped, however, due to personnel shortages. All supplies are on hand and work should resume in January 1982.

Detail Summary Sheet

Date: 5 Jan 82	Prot No: 22/79	Status: Ongoing

TITLE: Comparison of Control of Vasopressin Release from Isolated Hypothalamoneurohypophyseal (HNS) Explants Obtained from Normal and Hypertensive Rats

Start Date: Apr 79	Est Comp Date: Sep 83
Principal Investigator: John R. Claybaugh, Ph.D.	Facility: Tripler Army Medical Center
Dept/Sec: Clinical Investigation/Physiology	Associate Investigators: Kuuleialoha Cornette
Key Words: Hypothalamoneurohypophyseal explants Hypertension	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $4,500.	Periodic Review Results: Continue

OBJECTIVES: Certain rat models of hypertension have elevated pituitary content, plasma concentration, and urinary excretion rates of vasopressin. The mechanism for this increased release of vasopressin is not clear and may be due to an alteration in the sensitivity of the hypothalamus to various known stimuli. By removing the hypothalamus with the stalk connection to the neurohypophysis still intact, we can eliminate many uncontrollable inputs to vasopressin release and test the sensitivity to acetylcholine, angiotensin, and osmotic stimuli, and possibly others, in order to test the hypothesis.

TECHNICAL APPROACH: Five-week-old, male, spontaneously hypertensive rats will be selected from the colony at the Department of Clinical Investigation, Tripler Army Medical Center, Okamoto-Aoki strain. Age-matched normotensive male control rats will be of the WKY strain. The rats will be surgically prepared with indwelling carotid arterial cannulae and placed individually into metabolism cages. Two days after surgery, daily collections of urine will be started for analysis of flow rate, urine concentrations of Na+, K+ and antidiuretic hormone (ADH), and urine osmolality. Daily measurements of systolic and diastolic blood pressure will be made via the carotid arterial cannulae. After 5 days of measurements and urine collections, the rats will be sacrificed by guillotine and trunk blood collected for analysis of plasma osmolality, Na+, K+ and vasopressin concentration, and plasma renin activity. The HNS will be dissected and prepared for incubation. Osmolality will be determined by vapor pressure method, Na+ and K+ by flame photometry. Vasopressin will be assayed by radioimmunoassay and plasma renin activity by the New England Nuclear radioimmunoassay kit. All methods are ongoing in our laboratory.

Comparison of Control of Vasopressin Release from Isolated Hypothalamo-neurohypophyseal (HNS) Explants Obtained from Normal and Hypertensive Rats

PROGRESS: The surgical skills necessary for successful dissection of the HNS preparation and the procedures involved in organ culture have been routinely performed during the first 1½ years. We were able to demonstrate an osmotic stimulation of vasopressin from the HNS preparation in a 1-hour exposure period. Control experiments indicated a steady vasopressin production could be achieved during the necessary 5-hour block of time on the fourth day of organ culture. Changing the osmolality of the incubation medium from 290 to 315 mOsm/kg results in a significant increase in vasopressin release. Angiotensin at 10^{-5} M concentration also stimulated vasopressin release in this preparation. Having established these "standard" responses, we had confidence that the preparation was responding to normal physiological stimuli. Unfortunately, during the past year, inexplicably, we have been unsuccessful at reproducing these expected and necessary responses. Because the primary investigator on this project is a graduate student, it was felt that one year investment was all that could be afforded at this time and that a reassignment to a different thesis project was essential to her progress. Hopefully, this project will resume within one year.

Detail Summary Sheet

Date: 14 Jan 82	Prot No: 25/80	Status: Ongoing

TITLE: Urinary Metabolites of Vasopressin: Consequences in Radioimmunoassay

Start Date: Aug 80	Est Comp Date: Sep 82
Principal Investigator: John R. Claybaugh, Ph.D.	Facility: Tripler Army Medical Center
Dept/Sec: Clinical Investigation/Physiology	Associate Investigators: Aileen Sato Kuuleialoha Cornette
Key Words: Vasopressin	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $200.	Periodic Review Results: Continue

OBJECTIVES: To determine if a biologically inactive but immunologically detectable metabolite constitutes a significant amount of the vasopressin molecule excreted in the urine.

TECHNICAL APPROACH: Vasopressin has been shown to be metabolized in the renal nephron of some animals. Also, the values reported for the amount of vasopressin excreted in normal man varies greatly from one laboratory to the other. We have addressed the question as to whether the former results in the latter. Therefore, we have analyzed identical urine specimens from humans, dogs, rats, and pigs with two antisera which we have characterized as being specific to the "tail" or "ring' portion of the vasopressin molecule. If an immunological difference is determined, we will proceed in order to find out if a chemical difference is detectable. Thus, urine will be fractionated by various methods, including sephadex, electrophoresis, high pressure liquid chromatography (HPLC), ion exchange, ultrafiltration, and others. If two chemical identities can be shown that have immunological activity with one antibody but not the other, our results would clarify the need to use a specific type of vasopressin. Our hypothesis is that this is the case, and that a "ring" directed antibody detects more of the filtered vasporessin than a "tail" directed antibody and is therefore essential for the most accurate assessment of urinary vasopressin in excretion.

PROGRESS: Human, pig, rat, and dog urine contain immunologically detectable vasopressin that can be measured by both "tail" and "ring" directed antibodies, although in all species except the dog the amount measured by the "ring" directed antisera is about twofold greater than that detected by the "tail" directed antibodies. Although sephadex,

ion exchange, ultrafiltration, and proper electrophoresis have produced fractions of vasopressin that still yield immunologically different amounts of vasopressin, we have obtained only suggestive data that there are indeed two different chemical entities (possibly more) by electrophoresis. We have conducted a recent series of experiments on HPLC in which the "ring" directed antisera detects two peaks of activity, corresponding to arginine vasopressin. The "tail" directed antisera detects only the arginine vasopressin. The peak that we propose is a metabolite of vasopressin that has not been identified as yet, although pressinoic acid and deso-Gly (NH_2) arginine vasopressin have been ruled out, leaving des-Gly (NH_2)^9, des-Arg^8, arginine vasopressin as the probable metabolite. Proof will require the purchase of this synthetic analog and subsequent comparisons on HPLC.

Detail Summary Sheet

Date: 5 Jan 82	Prot No: 15/81	Status: Completed

TITLE: The Role of Dopamine in Angiotensin II Stimulated Antidiuretic Hormone Release

Start Date: Mar 81	Est Comp Date:
Principal Investigator: John R. Claybaugh, Ph.D.	Facility: Tripler Army Medical Center
Dept/Sec: Clinical Investigation/Physiology	Associate Investigators: David P. Brooks, Ph.D.
Key Words: antidiuretic hormone	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $2500.	Periodic Review Results:

OBJECTIVES: To determine whether dopamine is a neurotransmitter mediating angiotensin II stimulated ADH release.

TECHNICAL APPROACH: Angiotensin II was infused intravenously into conscious dehydrated dogs (n=6) at a rate of 10 ng/kg/min once by itself and once with a concurrent intravenous infusion of haloperidol (mg/kg/min), a dopamine antagonist. Plasma vasopressin, renin activity, and arterial blood pressure responses were compared between the two situations. Appropriate vehicle controls were also run on the same dogs.

PROGRESS: Angiotensin alone caused a tw -fold increase in plasma vasopressin concentration ($P<0.05$), a 25 mmHg increase in mean arterial blood pressure ($P<0.01$), and a 70% decrease in plasma renin activity ($P<0.01$). When haloperidol was simultaneously infused with angiotensin, plasma vasopressin concentration decreased about 20% (N.S.), while the changes in mean arterial blood pressure, +25 mmHg ($P<0.01$), and plasma renin acitivity, decrease of 65% ($P<0.01$), were similar to those observed with only angiotensin infused. The results suggest that a dopaminergic mechanism may be involved in the Angiotensin II-induced vasopressin release, but not its pressor actions or the negative feedback effects on renin release.

Brooks DP, Claybaugh JR: The Role of Dopamine in the Angiotensin II-Induced Vasopressin Release in the Conscious Dehydrated Dog. J Endocrinol (submitted).

Claybaugh JR and Brooks DP: The Role of Dopamine in the Angiotensin II-Induced Vasopressin Release in the Conscious Dehydrated Dog. Fed Proc (in press).

Detail Summary Sheet

Date: 5 Jan 82	Prot No: 21/81	Status: Terminated
TITLE: Postpartum Psychological Reactions to Childbirth Preparation and Experiences		
Start Date:		Est Comp Date:
Principal Investigator: CPT Wayne R. Coussens, MSC		Facility: Tripler Army Medical Center
Dept/Sec: Dept of Clinical Investigation		Associate Investigators: MAJ Clayton Shaw, MC
Key Words: Postpartum psychological reactions		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $300.	Periodic Review Results: Terminate

OBJECTIVE: To assess the psychological effects of childbirth preparation on mothers who "lose control" during labor and those who have cesarean births.

TECHNICAL APPROACH: Two hundred nulliparous expectant mothers will complete questionnaires at 32 weeks, 34 weeks, confirmed labor, 24 hours postpartum, and 6 weeks postpartum. Questionnaires will assess changes in relevant psychological and demographic characteristics. Mother, physician, and nurse ratings will be used to classify mothers on level of emotional control during labor and delivery. Classifications will also be made on reported levels of preparation for childbirth (psychoprophylaxis). Post hoc comparisons will be made between classifications across repeated measures to determine changes in relevant variables in relation to level of preparation for and level of emotional control in childbirth.

PROGRESS: The project is terminated due to the inability of the Department of Nursing to support it. The protocol will be revised and resubmitted.

Detail Summary Sheet

Date: 6 Jan 82 Prot No: 6/79 Status: Terminated
TITLE: Clinical Significance of Antidiuretic Hormone Levels in Disorders of Fluid and Electrolyte Metabolism

Start Date: Jun 80	Est Comp Date:
Principal Investigator: COL Samuel A. Cucinell, MC	Facility: Tripler Army Medical Center
Dept/Sec: Clinical Investigation	Associate Investigators: John R. Claybaugh, Ph.D.
Key Words: Antidiuretic hormone	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $4000.	Periodic Review Results: Terminate

OBJECTIVES: As a continuing part of our investigation into the influence of the antidiuretic hormone (ADH) in human metabolism, we wished to determine what influence this hormone has in a variety of clinical states.

TECHNICAL APPROACH: This study was designed to be a survey of occasional ADH levels in various clinical situations. Samples have been obtained in cirrhosis of the liver, nephrotic syndrome, renal failure, hypertension, congestive heart failure, pneumonia (particularly Legionnaires disease), and cardiac resusitation.

PROGRESS: This study is being terminated because it has yielded the maximal amount of information possible for the nature of the study. The clinical states have shown that ADH is elevated to varying degrees in Legionnaires disease, cirrhosis of the liver, congestive heart failure, and nephrotic syndrome. ADH has proven to be low in cardiac resusitation and gastrointestinal bleeding. The study suffers from lack of specific definition of the syndromes and incomplete design and accumulation of data. Each syndrome must be followed carefully in the clinical context for any clear-cut data to evolve. It is not surprising that ADH is elevated in pneumonia, cirrhosis, and heart failure. This data contributes little either to patient care or theory of practice. A systematic correlation of ADH with severity of these diseases may yield valuable information. The low ADH syndrome is more interesting. Patients who survive cardiac arrest, but with severe neurological deficit, seem to have depressed ADH, and one patient had diabetes insipidus. This has previously been reported, but not with ADH levels. All of these patients died eventually. The low ADH in gastrointestinal bleeding is artifact in that the samples were taken during treatment and suggest that ADH is an inconsistent hormone during this situation. Although this study is terminated because of poor design and incomplete data, it does provide suggestions for more valuable approaches.

Detail Summary Sheet

Date: 14 Jan 82 | Prot No: 2679 | Status: Ongoing

TITLE: Determination of Liver Blood Flow and Improved Technique for Sampling Hepatic Vein Blood

Start Date: Jul 79	Est Comp Date: Sep 82
Principal Investigator: COL Samuel A. Cucinell, MC	Facility: Tripler Army Medical Center
Dept/Sec: Clinical Investigation	Associate Investigators: Gordon R. Bryant
Key Words: Liver blood flow	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $2500.	Periodic Review Results. Continue

OBJECTIVE: To determine liver blood flow and to develop an improved technique for sampling hepatic vein blood.

TECHNICAL APPROACH: Methods now available for the determination of hepatic blood flow are either invasive or based on indirect chemical clearances. None of these methods is satisfactory for the accurate noninvasive quantitation of liver blood flow necessary for our continued studies into the lactic acid metabolism by the liver. It should be possible to place a thermistor catheter in the vena cava (VC) at the level of the renal and hepatic veins. Blood flow at these points might be determined by thermodilution. Hepatic vein blood flow could be estimated by subtraction of the blood flow in the vena cava at the level of the renal veins from the vena cava blood flow at the level of the diaphragm. This should be liver blood flow. It should be possible to sample pure hepatic vein blood by inflation of a balloon-equipped, double lumen catheter at the level just above the renal veins. This should cut off blood coming from the renal veins and below from entering the vena cava in the area of the hepatic veins. Blood samples from just above the balloon should be hepatic vein blood.

PROGRESS: The liver blood flow system has been reported in a preliminary manner in the Proceedings of the Western Pharmacology Society. 24:23-25, 1981. Additional work is being done comparing blood flow in the portal vein to hepatic vein before final publication. Details of engineering design are to be considered. The hepatic blood sampling device has been finalized and described in Proceedings of the Society for Experimental Biology and Medicine, 168:222-227, 1981.

Detail Summary Sheet

Date: 6 Jan 82 Prot No: 26/79 Status: Terminated
TITLE: Mechanism of Action and Antidote for Tricyclic Antidepressants

Start Date: Jul 79	Est Comp Date: Sep 82
Principal Investigator: COL Samuel A. Lucinell, MC	Facility: Tripler Army Medical Center
Dept/Sec: Clinical Investigation	Associate Investigators: LTC Barry M. Thomas, MC Bert Lum, Ph.D.
Key Words: Tricyclic antidepressants	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $200.
	Periodic Review Results: Terminate

OBJECTIVES: To try to define more precisely the cardiovascular toxicity of the tricyclic antidepressants and to suggest the most rational antidote for the cardiotoxicity.

TECHNICAL APPROACH: An animal model of cardiotoxicity of the TCA will be developed in the dog and rabbit. The animal will be sedated with the TCA itself. Recordings of the EKG, electrolytes, and blood gases will be made. Doses of TCA will be given to produce EKG toxicity. In some animals it will be necessary to allow the complete cardiotoxicity to evolve in order to determine the pattern of conduction abnormality leading to cardiac arrest. Once this pattern is defined, antidotes and mechanisms of altering the EKG pattern will be made. It is anticipated that a drug so rich in autonomic actions would have a cardiac effect which would operate through the autonomic nervous system. Blockade of this system at known points, i.e., ganglionic blockade, cholinergic receptor blockade, adrenergic transmitter and receptors blockade, as well as autonomic stimulants at the same levels, should alter the pharmacological pattern of TCA. If the TCA proves resistant to these manipulations, a direct quinidine-like action may exist and direct pacing may be of value.

PROGRESS: The project is terminated. The University of Hawaii group is pursuing the study alone.

Detail Summary Sheet

Date: 5 Jan 82 Prot No:8/81 Status: Completed
TITLE: Fansidar Prophylaxis in New Guinea

Start Date: Sep 80	Est Comp Date:
Principal Investigator: COL Samuel A. Cucinell, MC	Facility: Tripler Army Medical Center
Dept/Sec: Dept of Clinical Investigation	Associate Investigators:
Key Words: Malaria	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $300.
	Periodic Review Results:

OBJECTIVE: This is a preliminary study to design the most reasonable prophylaxis for malaria in individuals who will be exposed to both high altitude and malaria sequentially or simultaneously.

TECHNICAL APPROACH: A group of seven active Army personnel explored the mountainous areas of New Guinea for location of downed aircraft sites at altitudes up to 9000 feet. With regard specifically to malaria they were given Fansidar to be taken before leaving for New Guinea and at monthly intervals thereafter. The following laboratory tests were done before and after their tour in New Guinea: CBC, urinalysis, SMA-20, glucose-6 phosphate dehydrogenase determination, and sickle cell preparation. Malaria smears were done upon return.

PROGRESS: The 9-week mission was completed with one member removed to Hawaii because of leg trauma. One man who was allergic to sulfa drugs took CP tablets, one per week. There were no illnesses or fever. It was noted that the local inhabitants took CP tablets rather than Fansidar when they entered malaria regions of New Guinea. Although malaria was present in the area, the members of this team had no direct contact with known cases. The preliminary studies done at Tripler Army Medical Center showed all men had normal renal, hepatic, and hematologic function. All of the laboratory tests were repeated upon return to Hawaii and were found to be normal. Thick smears were done on all members and no malaria was seen. Under the conditions used, Fansidar caused no toxicity or complication in men operating at high altitude for short periods of time. No toxicity was noted.

Detail Summary Sheet

Date: 6 Jan 82	Prot No: 17/79	Status: Terminated

TITLE: Biodetermination of Scombroid Toxin

Start Date: 1 Jul 79	Est Comp Date:
Principal Investigator: CPT Clayton L. Hadick, VC	Facility: Tripler Army Medical Center
Dept/Sec: Clinical Investigation/Veterinary Svc	Associate Investigators:
Key Words: Scombroid toxin	

Accumulative MEDCASL Cost:	Est Accumulative OMA Cost: $500.	Periodic Review Results: Terminate

OBJECTIVES: To design a bioassay to determine presence of unknown toxin in fish responsible for clinical scombroid poisoning. This will be attempted by correlating known patients, fish, specimens, and suspected outbreaks.

TECHNICAL APPROACH: A bioassay will be developed which may utilize radioative tagged human serum used in rabbits. Intradermal injections of the fish extract gives a "wheal and flare" which can be measured by amount of radioactivity in the area. This is most tentative. Other possibilities would include oral ingestion in laboratory animals with modified guts to watch for histamine-type response. Whatever test we develop will be correlated with retrospective analysis of the 30 to 50 cases seen in Hawaii in the last two years. The fish specimens come from these suspected cases. In addition, the investigator has made arrangements to be notified as soon as possible about any new suspected cases.

PROGRESS: It has been found that it is not practical to do this study at TAMC and it is therefore terminated.

Detail Summary Sheet

Date: 23 Dec 81	Prot No: 17/81	Status: Completed

TITLE: Intraocular Prosthesis in a Cynomolgous Monkey (Macaca fascicularis)

Start Date: Mar 81		Est Comp Date:
Principal Investigator: CPT Clayton L. Radick, VC		Facility: Tripler Army Medical Center
Dept/Sec: Clinical Investigation/Veterinary Svc		Associate Investigators:
Key Words: Cynomolgous monkey Intraocular prosthesis		
Accumulative PEDCASE Cost:	1st Accumulative ONA Cost: $1000.	Periodic Review Results:

OBJECTIVE: To determine long-term toxicity and acceptance of an intraocular prosthesis in a primate. Also, to determine aesthetic presentability of such a device.

TECHNICAL APPROACH: To publish data on intraocular prosthesis in primates. A human prosthesis was used to determine the efficacy of this procedure in primates and the long-term toxic effects.

PROGRESS: This project was presented at the annual meeting of the American Association of Laboratory Animal Science, Salt Lake City, Utah, in September 1981. A manuscript is in preparation.

Detail Summary Sheet

Date: 4 Jan 82 Prot No: 46/78 Status: Completed
TITLE: Lactic Metabolism in Isolated Liver Cells with Regard to Anoxia, Alkalosis, and Temperature

Start Date: Nov 78	Est Comp Date:
Principal Investigator: CPT John C. O'Brien, MSC	Facility: Tripler Army Medical Center
Dept/Sec: Clinical Investigation/Biochemistry	Associate Investigators: COL Samuel A. Cucinell, MC
Key Words: Lactic metabolism	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $8000.
	Periodic Review Results:

OBJECTIVES: To study lactate metabolism in primary cultures of rat hepatocytes.

TECHNICAL APPROACH: Earlier in the study we characterized lactate metabolism in monolayer cultures of rat hepatocyte cells and determined that neither anoxia nor pH would account for the apparent production of lactate seen by liver during hemorrhagic shock. We wished to further study liver carbohydrate metabolism under conditions of endotoxic shock.

PROGRESS: While anoxia and acidosis inhibit lactate consumption in hepatocyte cultures, endotoxin was found to have no direct effect when added to the medium. Cells prepared from endotoxic shocked rats, however, were unable to metabolize lactate. It appears the effect of endotoxin on liver carbohydrate metabolism cannot be explained by a direct effect on the hepatocyte cell. These results are being prepared for publication.

"Effect of pH, PO_2 and PCO_2 on Lactate Consumption by Hepatocytes," presented at the 64th Annual Meeting of the Federation of American Societies for Experimental Biology, Anaheim, California, April 1980.

O'Brien, J. C. and Cucinell, S. A.: Effects of Anoxia, Acidosis, and Endotoxin on Glucose, Lactate, and Indocyanine Green Metabolism in Primary Hepatocyte Culture. Proc West Pharmacol Soc 24:123-125, 1981.

O'Brien, J. C. Jr. and Cucinell, S. A.: Lactate Consumption by Hepatocytes in Monolayer Culture. Proc Soc Exp Biol Med 166:413-417, Mar 1981.

"Endotoxin Effects of Rat Hepatocytes in Monolayer Culture," presented at the 65th Annual Meeting of the Federation of American Societies for Experimental Biology, Anaheim, CA, April 1981.

Detail Summary Sheet

Date: 12 Jan 82 Prot No: 29/79 Status: Ongoing
TITLE: The Behavioral Effects of Antihypertensive Therapy in the Elderly

Start Date: Aug 80	Est Comp Date: Jun 82
Principal Investigator: LTC John L. Aoki, MC	Facility: Tripler Army Medical Center
Dept/Sec: Dept of Family Practice	Associate Investigators: Marvelu Peterson, R.N. COL Samuel A. Cucinelli, MC
Key Words: Antihypertensive therapy	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $750.	Periodic Review Results: Continue

OBJECTIVES: To determine if treatment with antihypertensive medications in elderly hypertensive subjects produces changes in measurable areas of behavioral performance. If behavioral changes occur, does the direction of change reflect improved or impaired function?

TECHNICAL APPROACH: Elderly hypertensive patients will be placed on an alternating regimen of active antihypertensive medications and placebos. Data on blood pressure response to the two different treatments and behavioral tests and outcomes will be collected at the end of each four-week period. The two groups of subjects will be matched as closely as possible and differ only in the order in which the treatment, active medications, or placebos are given. The behavioral outcomes are conceptualized as being directly influenced by the independent variable of medication status and indirectly by the intermediate variable, blood pressure. Blood pressure is directly influenced by the independent variable, medication status.

PROGRESS: The study protocol has now been completed on a total of 19 patients, utilizing two study groups over an 8-week study interval. Three patients were withdrawn from the study. One was diagnosed as having a colon carcinoma and subsequently underwent a partial colectomy. The second patient's blood pressure reached the study limit and she was placed on her active antihypertensive medication with no complications as her blood pressure stabilized. The third patient had chest pain suspicious for angina. Subsequent follow-up and evaluation proved to be normal and she resumed her vigorous exercise program. The investigators are planning two more groups of 16 patients each, which will bring the total number to over 50 patients. This will allow valid statistical analyses to be performed.

The primary problems encountered in the study have been lack of clerical and administrative assistance. Pharmacy and clinical laboratory support have thus far been excellent.

Because one of the investigators will be leaving the Army, CPT Charles L. Henley has volunteered to assume responsibility for the medical care of the study patients. A Family Practice third-year resident has also expressed interest in the study and he has been given time to participate in this research. As more interest in research is being generated within the Department of Family Practice, it is hoped that this will be an ongoing departmental undertaking.

Detail Summary Sheet

Date: 30 Oct 81	Prot No: 4/80	Status: Ongoing

TITLE: Evaluation of PUVA in the Treatment of Resistant Psoriasis

Start Date: Aug 80	Est Comp Date: Indefinite
Principal Investigator: COL Harold I. Albert, MC	Facility: Tripler Army Medical Center
Dept/Sec: Dept of Medicine/Dermatology	Associate Investigators: LTC Philip Chan, MC MAJ Richard Gentry, MC
Key Words: Psoriasis	

Accumulative MEDCASE Cost:	Est Accumulative GNA Cost: $500.	Periodic Review Results: Continue

OBJECTIVE: To determine the potential benefits of PUVA in the treatment of psoriasis resistive to other forms of therapy.

TECHNICAL APPROACH: In August 1980 a clinical investigation of the efficacy of psoralen plus long wave ultra-violet light in the treatment of severe psoriasis was approved. The project was included under IND #12,941 with approval of COL Charles Lewis, BAMC, principal investigator. The protocol is essentially the same as that being used by several major study groups.

PROGRESS: Two patients have been enrolled in the study. Both have had essentially complete clearing of psoriasis and now are on maintenance therapy with PUVA.

Detail Summary Sheet

Date: 23 Dec 81	Prot No: 1/81	Status: Terminated

TITLE: A Prospective Trial of Propranalol in Patients with Diffuse Toxic Goiter for Subgroup Determination

Start Date:		Est Comp Date:
Principal Investigator: CPT William T. Highfill, MC		Facility: Tripler Army Medical Center
Dept/Sec: Dept of Medicine/Endocrine		Associate Investigators:
Key Words: Goiter, toxic		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $300.	Periodic Review Results: Terminate

OBJECTIVES: To determine if there is a predictable subgroup of patients with diffuse toxic goiter whose disease undergoes remission during and following treatment with propranolol.

TECHNICAL APPROACH: Patients with diffuse toxic goiter will be given propranolol, 80 mg orally 3 times a day for 6 months, after which the medication will be discontinued and the patient followed for 3 months or until clinical symptoms and/or laboratory evidence of thyrotoxicosis recur. At the end of the trial, the data of all patients who remain clinically and chemically euthyroid will be compared to that of the rest of the trial group to determine if there are any characteristics or responses to propranolol which might distinguish this subgroup.

PROGRESS: This project has been terminated as it has not been approved by OTSG.

Detail Summary Sheet

Date: 23 Dec 81	Prot No: 2/81	Status: Completed

TITLE: Coronary Arteriography in the Army

Start Date. Dec 80	Est Comp Date: Dec 81
Principal Investigator: CPT William T. Highfill, MC	Facility: Tripler Army Medical Center
Dept/Sec: Dept of Medicine/Cardiology	Associate Investigators: LTC Harry M. Thomas, MC
Key Words: Coronary arteriography	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $300.	Periodic Review Results:

OBJECTIVE: To explore the use of coronary arteriography in Army medicine, to evaluate certain technical aspects of the procedure, and to better define the nature of coronary artery disease in the active duty population.

TECHNICAL APPROACH: This is a collaborative Army study coordinated by MAJ John M. Harris, MC, of Madigan Army Medical Center, consisting of a one-year prospective chart review of the catheterization data at each center.

PROGRESS: The study has been completed with approximately 200-250 patients in the study. Data is currently being analyzed.

Detail Summary Sheet

Date: 6 Jan 82 Prot No: 19/81 Status: Ongoing
TITLE: Dexamethasone Antiemetic Study for Chemotherapy Patients

Start Date:	Est Comp Date:
Principal Investigator: LTC Charles F. Miller, MC	Facility: Tripler Army Medical Center
Dept/Sec: Dept of Medicine	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $300.	Periodic Review Results:	Awaiting OTSG approval

OBJECTIVES: To determine the effectiveness of Dexamethasone in preventing or alleviating nausea and vomiting in cancer patients receiving chemotherapeutic agents.

TECHNICAL APPROACH: A double-blind study of each participating patient will be performed. Patients will be obtained from adult oncology clinic. No minors will be included in the study. Each patient will receive an envelope from the pharmacy containing three tablets of either placebo or Decadron, 4 mg. The tablets are to be taken at lunch the day before therapy, at bedtime the day before therapy, and the morning of therapy. All additional standard antiemetics will be continued since neither the patient nor the invetigator has any way of knowing if the active Decadron was taken. The patients will be asked to score their nausea and other symptoms and the vomiting will be objectively followed by the clinic staff.

PROGRESS: Awaiting OTSG approval.

Detail Summary Sheet

Date: Jan 82	Prot No: 7/81 Status: Terminated
Title: Evaluation of Lower Gastrointestinal Bleeding: Colonoscopy Alone vs Colonoscopy as an Adjunct to Barium Enema and Proctoscopy	
Start Date:	Est Comp Date:
Principal Investigator: LTC Robert L. Myers, MC	Facility: Tripler Army Medical Center
Dept/Sec: Medicine/Gastroenterology	Associate Investigators: COL Charles C. Jones, MC
Key Words: Gastrointestinal Bleeding	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $300.
	Periodic Review Results: Terminate

OBJECTIVE: This study will compare colonoscopy with a multimodality evaluation of occult and overt rectal bleeding.

TECHNICAL APPROACH: All patients presenting to the Gastroenterology Clinic and Proctoscopy Clinic with a complaint of overt or occult rectal bleeding will be eligible for this study. Patients must meet the following criteria: (a) have a history of bright red rectal bleeding or the discovery of occult rectal bleeding in the previous six weeks; (b) be 40 years of age or older; (c) be capable of informed consent; (d) must not have had proctoscopic or barium enema in the preceding six weeks. After inclusion in the study groups, all patients will be interviewed by one of the principal ivnestigators. Demographic and historical data will be collected. A CBC, clotting profile, and hemoccult screen will be collected on each patient. Patients will be randomized. One group will have colonoscopy alone. The other group will have proctoscopic examination, air contrast barium enema, and colonoscopy. All negative colonoscopies will be compared as to patient comfort, diagnostic rates, complications, and time of workup.

PROGRESS: This project is terminated due to lack of time on the part of the investigators.

Detail Summary Sheet

Date: 5 Jan 82	Prot No: 81/81	Status: Completed

TITLE: The Influence of pH and Serum Protein Concentration on the Anion Gap

Start Date: Jan 81	Est Comp Date:
Principal Investigator: CPT William D. Paulson, MC	Facility: Tripler Army Medical Center
Dept/Sec: Dept of Medicine	Associate Investigators:
Key Words: Anion gap	
Accumulative MIPCASI Cost:	Est Accumulative OMA Cost: $2000.
	Periodic Review Results:

OBJECTIVES. To determine how the acidity and alkalinity of blood and its protein concentration influence the relationship of the serum chemistries (e. g., Na, K, Cl, HCO_3) to each other.

TECHNICAL APPROACH: Fourteen dogs were studied for changes in the in vivo ionization of plasma protein during respiratory acidosis and respiratory alkalosis. No effort was made to change the serum albumin concentration.

PROGRESS: The undetermined anion gap was unchanged at the extreme of acidosis and alkalosis suggesting that the ionization of plasma protein does not change ionization with pH. A manuscript is in preparation.

Detail Summary Sheet

Date: 30 Dec 81	Prot No: 25/80	Status: Terminated

TITLE: Pulmonary Function in Patients with Gastroesophageal Reflux

Start Date:		Est Comp Date:
Principal Investigator: MAJ Rosemary F. Rodgers, MC		Facility: Tripler Army Medical Center
Dept/Sec: Dept of Medicine/Pulmonary		Associate Investigators: COL Charles C. Jones, MC MAJ Anna L. Chacko, MC LTC George E. Underwood, MC
Key Words: Esophageal reflux		
Accumulative MEDCASE Cost: $2000.	Est Accumulative OMA Cost: $300.	Periodic Review Results: Terminate

OBJECTIVE: To determine whether there are significant abnormalities in the pulmonary function studies of nonsmoking patients diagnosed to have gastroesophageal reflux.

TECHNICAL APPROACH: Diagnosis of gastroesophageal reflux in nonsmoking adults will be established by (1) clinical history (with particular attention to symptoms of reflux and pulmonary disease) and physical examination, (2) barium esophagram, and (3) gastroesophageal scintiscan. Incidence of pulmonary disease in these individuals will be determined by (1) PA and lateral chest roentgenogram, (2) spirometry with and without bronchodilator (0.5 cc Isuprel in 2 cc NS), (3) gas dilution lung volume studies, (4) DLCOSB, and (5) body plethysmographic determination of FRC, RAW, lung compliance, and pulmonary elastic recoil. At conclusion of the clinical studies, results will be examined to determine the extent of cause and effect relationship between gastroesophageal reflux and pulmonary disability.

PROGRESS: This project is terminated due to departure of principal investigator.

Detail Summary Sheet

Date: 15 Jan 82	Prot No: 2/79	Status: Ongoing

TITLE: Glucose Modulation of Insulin Binding

Start Date: Jan 79	Est Comp Date: Sep 82
Principal Investigator: MAJ Shiao W. Shen, MC	Facility: Tripler Army Medical Center
Dept/Sec: Dept of Medicine/Endocrine	Associate Investigators:
Key Words: Insulin Binding	

Accumulative MEDCAST Cost: $1500.	Est Accumulative IMA Cost: $1000.	Periodic Review Results: Continue

OBJECTIVES: To investigate the effect of glucose concentration on insulin binding; to investigate the effect of glucose preincubation on insulin binding; and to study glucose transport under varying insulin and glucose concentrations.

TECHNICAL APPROACH: Epididyral fat pads are removed from male Sprague-Dawley rats. Isolated fat cells are prepared by shaking at 37° C for 60 minutes in Krebs-Ringer bicarbonate buffer containing collagenase (3 mg/ml) and albumin (40 mg/ml) by the method of Rodbell. Isolated fat cells are then suspended in a buffer containing 35 mM Tris, 120 mM NaCl, 1.2 mM $MgSO_4$, 2.5 mM KCl, 1% bovine serum albumin, pH 7.6, and varying concentrations of glucose in a Dubnoff metabolic shaker at 37° C for 45 minutes. At the end of incubation, cells are washed and ready to be used for either ^{125}I-insulin or glucose transport studies. ^{125}I-insulin binding is carried out with ^{125}I-insulin prepared at a specific activity of 100-150 μCi/μg according to the Freycht et al. modification of the method of Hunter and Greenwood. Glucose transport studies are carried out by incubating cells with 2-deoxy-II-^{14}C-D-glucose (specific activity 2 mCi/mM) in Krebs-Ringer bicarbonate, pH 7.4, containing bovine serum albumin (10 mg/ml) at 24° C. This assay measures the total uptake of the radio-labeled 2-deoxy-glucose and is based on the principle that while 2-deoxy-glucose is transported and phosphorylated by the same process as D-glucose, it cannot be further metabolized. Calculation of glucose transport is based on the method of Olefskey.

PROGRESS: After many attempts, the cultured fibroblasts from the foreskin obtained during circumsion has proved to be an appropriate system to use. However, since the departure of MAJ O'Brien, the investigation has been temporarily suspended until another Ph.D. biochemist arrives since there is the possibility of overgrowth of virus in the culture medium.

Detail Summary Sheet

Date: 30 Dec 81 Prot No: 3/79 Status: Completed
TITLE: Free and Total Insulin Levels in Insulin-Treated Diabetics

Start Date: Feb 79	1st Comp Date: Sep 81
Principal Investigator:	Facility:
MAJ Shiao W. Shen, MC	Tripler Army Medical Center
Dept/Sec:	Associate Investigators:
Dept of Medicine/Endocrine	
Key Words:	
Insulin Binding	
Accumulative MILCASE Cost:	1st Accumulative O&M Cost: $1000.
	Periodic Review Results

OBJECTIVES: To measure free and total insulin level in treated diabetics, to characterize the insulin-binding antibodies in the patients and to correlate the free insulin levels and the characteristics of the insulin-binding antibodies to control of diabetes.

TECHNICAL APPROACH: Patients were classified with regard to their diabetic control on the basis of personal knowledge, examination of the clinical notes, and 24-hr urine glucose. Heparinized blood, 15 ml, was drawn from subjects after an overnight fast and again at 4 pm for plasma glucose, insulin determinations, and characterization of insulin antibodies. Free insulin and total insulin were extracted by a modified method of Nakagawa et al. Radioimmunoassay for free insulin and total insulin were done by dextran-coated charcoal method. Deinsulinization was accomplished by combining one part plasma with 1.25 (V/V) 0.12N HCL and 0.5 parts dextran-coated suspension. The mixture was Vortex-mixed before adding 1.25 parts 0.12 N NaOH and centrifuging twice at 2500 rpm for 30 minutes at 4°C to completely remove the charcoal particles with the adsorbed insulin. The supernatant was also used for binding assay to characterize the insulin antibodies.

PROGRESS: It was found that (1) there is no relationship between administered insulin dosage and free insulin levels in diabetic patients. (2) insulin binding to monocytes is not correlated with bound insulin or insulin dosage, but is inversely correlated to free insulin level, and (3) the maximum binding sites of insulin antibody are inversely proportional to the ratio of free/bound insulin.

This study is to be presented at the annual meeting of Military Endocrinologists in June 1982 in conjunction with the annual meeting of the Endocrine Society and American Diabetic Association.

Detail Status Sheet

Date: 6 Jan 82 Prot No: 1370 Status: Terminated
TITLE: Evaluation of Heparin in Pericardial Effusion

Start Date:	1st Comp Date:
Principal Investigator:	Facility:
CPT Roger L. Siddoway, MC	Tripler Army Medical Center
Dept/Sec:	Associate Investigators:
Dept of Medicine/Cardiology	LTC Barry M. Thomas, MC
Key Words:	COL Samuel A. Cucinell, MC
Pericardial effusion	

Accumulative RELEASE Cost:	Est Accumulative GMW Cost: $300.	Periodic Review Results: Terminate

OBJECTIVES: To determine the indications for continued anticoagulation in pericarditis in myocardial infarction.

METHODOLOGICAL APPROACH: All patients with established myocardial infarction and pericardial friction rubs will be eligible for this study. After having informed consent, the patient will be entered into a randomized double blinded study. The pharmacy will send to the critical care unit appropriate intravenous solution containing heparin or not, but labeled as 'heparin study--contact pharmacy.' The physicians caring for the patient will not be blinded and will control the PT/PTT according to current standards if the patient does get heparin (or whose heparin is continued). An echocardiogram and a phonocardiogram will be taken daily on all patients in the study (by the investigators who will be blinded). The attending physicians will be advised daily of the fluid content of the pericardial sac. A decision to break the code and terminate the study will be made by a consultant cardiologist noninvestigator. Dressler syndrome is an indication to stop heparin. Anticoagulation with coumadin will be instituted or continued according to current practice and the heparin will be discontinued at the appropriate time in the group continued on anticoagulation. A placebo will be started in nonanticoagulated patients at the appropriate time.

PROGRESS: Because of delay in approval, this protocol has been terminated.

Detail Summary Sheet

Date: 23 Dec 81	Prot No: 19/79	Status: Terminated	
TITLE: Beta Blocker Heart Attack Trial			
Start Date:		Est Comp Date:	
Principal Investigator: LTC Harry M. Thomas, MC		Facility: Tripler Army Medical Center	
Dept/Sec: Dept of Medicine/Cardiology		Associate Investigators:	
Key Words: Beta blocker Propranolol Heart attack			
Accumulative PLEASE Cost:	1st Accumulative OMA Cost: $300.	Periodic Review Results: Terminate	

OBJECTIVES: To determine the efficacy of propranolol in decreasing the incidence of sudden death and/or recurrent myocardial infarction.

TECHNICAL APPROACH: Uncomplicated postinfarction patients are treated prospectively with placebo or Inderal to see if survival in these patients is prolonged by prophylactic therapy with a beta-blocker.

PROGRESS: The national study of which this was to be a part has been terminated.

Detail Summary Sheet

Date: 23 Dec 81	Prot No: 33/79	Status: Ongoing

TITLE: Evaluation of Amiodirone Therapy of Cardiac Arrhythmias

Start Date:		Est Comp Date:
Principal Investigator: LTC Harry M. Thomas, MC		Facility: Tripler Army Medical Center
Dept/Sec: Dept of Medicine/Cardiology		Associate Investigators:
Key Words: Amiodirone Arrhythmia		
Accumulative MEDCASE Cost:	Est Accumulative CMA Cost: $300.	Periodic Review Results: Continue

OBJECTIVES: To control symptomatic cardiac arrhythmias which have not been responsive to the conventional and accepted forms of treatment or whose control is dependent on the use of a drug which has been shown to be harmful to or in other ways not tolerated by the individual.

TECHNICAL APPROACH: Amiodirone, an investigational drug, is utilized to treat supraventricular and ventricular arrhythmias which are refractory to other drugs. All results are pooled with othe Army installations utilizing Amiodirone therapy. The collecting facility for this data is Letterman Army Medical Center.

PROGRESS: At TAMC, two patients are currently on Amiodirone. One patient had a breakthrough of her recurrent ventricular tachycardia when she personally reduced her dosage of medication to 400 mg daily. Increase in Amiodirone to 800 mg daily has prevented recurrence of her arrhythmia. The second patient has complete control of his arrhythmia. Both patients have developed minimal side effects in the form of corneal micro deposits which do not interfere with vision. Neither patient has developed significant complications with the medication. In the overall Army series, several patient have had to discontinue the drug because of reversible peripheral neuropathy and reversible pulmonary fibrosis.

Detail Summary Sheet

Date: 4 Jan 82 Prot No: 35/80 Status: Ongoing

TITLE: Improved Record Keeping in the MICU/CCU by Means of Table Model Computers

Start Date: Sep 80	Est Comp Date: Sep 82
Principal Investigator:	Facility:
CPT Harry H. Thomas, MC	Tripler Army Medical Center
Dept/Sec:	Associate Investigators:
Dept of Medicine/Cardiology	MAJ Klaus Cierke, MC
Key Words:	COL Samuel J. Cucinell, MC
Record Keeping	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $4000.	Periodic Review Results: Continue

OBJECTIVE: To increase diagnostic sensitivity by modern graphic display of clinical data.

TECHNICAL APPROACH: The Hewlett Packard 9835A computer will be programmed to display quantitative data generated by selected patients. The displays will be graphic and organized similar to data in clinical journals and textbooks. The graphic displays will include all of the quantitative clinical data generated on the patients together with timed notations of the clinical progress of the patient (including drug therapy, invasive procedures, new diagnoses, etc.) After sufficient number of patients have been studied, a quasi-objective evaluation will be performed in which a physician not associated with the patient will review the patient's chart in the classic manner compared to review of the patient's chart in addition to the graphic displays. The physicians will list the diagnosis for each day of ICU hospitalization. Statistical analysis will be by diagnosis made by physicians doing alternate type of chart review by χ^2.

PROGRESS: Additional memory and software have been obtained and initial programs are to be undertaken.

Detail Summary Sheet

Date: 7 Jan 82 Prot No: 9/80 Status: Ongoing
TITLE: Comparison of Daily Versus Alternate Prednisone Therapy in Pulmonary Sarcoidosis

Start Date: Mar 80 1st Accrual:
Principal Investigator: Facility:
MAJ George L. Underwood Jr., MC Tripler Army Medical Center
Dept/Sec: Associate Investigators:
Dept of Medicine/Pulmonary Disease
Key Words:
Pulmonary sarcoidosis

Accumulative MEDCASE Cost: Est Accumulative OMA Cost: $300. Periodic Review Results: Continue

OBJECTIVES: To compare the relative efficacy of equivalent dose daily vs alternate-day Prednisone therapy in stage II sarcoidosis patients with functional impairment. Techniques of evaluation must be practical and widely applicable in clinical use.

CLINICAL APPROACH: In order to compare the therapeutic effects and complications of alternate day Prednisone to daily Prednisone in patients with sarcoid, a six-month cooperative, alternate allocation, unblinded study has been adopted. Both methods of Prednisone dosing are used clinically, but with only anecdotal and personal experience type data to evaluate, it is impossible to select the best treatment for this disease.

PROGRESS: The multicentric study on pulmonary sarcoidosis performed under the auspices of principal investigators at WRAMC continues. To date Tripler has entered seven patients in the study. Follow-up continues on the majority of these patients, although several are being followed at other Army institutions because of PCS. The criteria for selection and actual performance of the study remain unchanged.

Detail Summary Sheet

Date: 6 Jan 81	Prot No: 82/81	Status: Ongoing

TITLE: Antibiotic Prophylaxis in Vaginal Hysterectomy: A Comparison of Different Regimens; Single Dose, Multidose and Intraoperative Irrigation with Cefamandole Nafate

Start Date:	Est Completion:
Principal Investigator: CPT Thomas W. Burke, MC	Facility: Tripler Army Medical Center
Dept/Sec: Dept of Obstetrics and Gynecology	Associate Investigators:
Key Words: Vaginal hysterectomy	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $300.	Periodic Review Results:	Awaiting approval

OBJECTIVE: To determine the efficacy of different parenteral antibiotic regimens compared with intraoperative antibiotic irrigation in decreasing the febrile morbidity and the sequelae secondary to pelvic cellulitis following vaginal hysterectomy.

TECHNICAL APPROACH: Study proposed is a prospective blinded study designed to compared antibiotic prophylaxis, single-dose parenteral, and multidose parenteral in decreasing the incidence of infectious morbidity following vaginal hysterectomy.

PROGRESS: Awaiting HSG approval.

Detail Summary Sheet

Date: 15 Jan 82	Prot No: 18/80	Status: Ongoing	
TITLE: Animal Surgery as Adjunct to Gynecology Residency Program			
Start Date: 1 June 1980		1st Comp Date:	
Principal Investigator:		Facility:	
CPT Marshall L. Matthews, MC		Tripler Army Medical Center	
Dept/Sec:		Associate Investigators:	
Dept of Obstetrics and Gynecology		CPT Clayton L. Hadick, VC	
Key Words:			
Training			
Gynecological surgery			
Accumulative MEDCASE Cost:	Est Accumulative ONA Cost: $3,500.	Periodic Review Results: Continue	

OBJECTIVES: To perfect skills and increase exposure and proficiency in gastrointestinal, genitourinary and vascular procedures.

TECHNICAL APPROACH: Dogs have end-to end anastomosis, side-to-side anastomosis, diverting colostomies, end-to-end ureteral anastomosis, and ureteral implantation as well as retropelvic vessel dissection and node dissection.

PROGRESS: The project continues as a training protocol. Surgery was done on 25 dogs and 29 residents were trained in the procedure.

Detail Summary Sheet

Date: 20 Jan 82 Prot No: 40/78 Status: Ongoing
TITLE: Microsurgical Anastomosis of the Rabbit Oviduct

Start Date: 1 Oct 78	Est Comp Date
Principal Investigator: LTC Heinz O. Osterholzer, MC	Facility: Tripler Army Medical Center
Dept/Sec: Dept of Obstetrics and Gynecology	Associate Investigators:
Key Words: Training Microsurgery	

Accumulative RELEASE Cost:	Est Accumulative OMA Cost:$2000.	Periodic Review Results: Continue

OBJECTIVES: To perfect skills and increase proficiency in microsurgical techniques.

TECHNICAL APPROACH: Bilateral ligation of the fallopian tubes with microsurgical reconstruction is performed in rabbits. The reconstruction is either bilateral or unilateral.

PROGRESS: The project continues as a training protocol. Surgery was done on eight rabbits and ten residents were trained in the procedure.

Detail Summary Sheet

Date: 18 Jan 82	Prot No: 12/81	Status: Ongoing

TITLE: The Cold Pressor Test as a Predictor of Pregnancy-Induced Hypertension

Start Date: June 81	Est Comp Date: June 82
Principal Investigator: LTC Heinz Osterholzer, MC	Facility: Tripler Army Medical Center
Dept/Sec: Obstetrics and Gynecology	Associate Investigators: Florentino V. Acalanza, M.D. LTC John F. Read, MC
Key Words: Cold pressor test Hypertension	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $300.
	Periodic Review results: Continue

OBJECTIVE: To develop a convenient means of detecting the patient destined to develop pregnancy-induced hypertension (PIH).

TECHNICAL APPROACH: All healthy, normotensive, nulliparous women attending the Obstetrics Clinic, TAMC, will be asked to participate in this study. Those women with a past history of chronic hypertension, renal disease, and cold allergy will be excluded from the investigation. During each visit, each subject will be evaluated for hyperreflexia, edema, proteinuria, and weight gain. Each subject will be tested with the cold pressor test in accordance with the protocol of Hines and Brown as described above, with the following modifications. The supine position will be avoided; the subject will rest in bed in a semi-reclining position (30^{0}) with a slight left lateral tilt. An electronic fetal monitoring unit will be used continuously during the entire test period to externally monitor the fetal heart rate and the uterine activity. A reactive fetal heart rate pattern and absence of uterine contractions will be a prerequisite for proceeding to the cold pressor test. The subject's pulse rate will also be continuously monitored. Urinalysis for proteinuria will be done before and after the cold pressor test. Each subject will initially be tested at 28 to 30 weeks' gestation and again at 34 weeks' gestation. The subjects will then be followed again routinely in the Obstetrics Clinic and eventually in Labor and Delivery, and the presence or absence of PIH will be noted. Hyperreactors will be retested 3 months after delivery.

PROGRESS: Only one patient has been entered in the study thus far. Problems have been encountered with recruiting of volunteers due to lack of support by residents. The principal investigator plans to personally recruit volunteers in the future.

Detail Summary Sheet

Date: 18 Jan 82	Prot No: 9/81	Status: Ongoing

TITLE: Randomized Trial of Ambulation vs Oxytocin for Labor Enhancement

Start Date:	Est Comp Date:
Principal Investigator:	Facility:
LTC John A. Read, MC	Tripler Army Medical Center
Dept/Sec:	Associate Investigators:
Obstetrics and Gynecology/Obstetrics	
Key Words:	
labor enhancement	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $300.	Periodic Review Results: Continue

OBJECTIVE: To compare the efficacy of ambulation vs oxytocin in cases of dysfunctional labor, so-called dystocia.

TECHNICAL APPROACH: 100 patients will be studied. All patients with demonstrated failure to progress in labor for one hour, are at least 4 cm dilated, and who are felt to require augmentation of labor are eligible for the study. Patients will be randomized into two groups, one utilizing ambulation and the other utilizing oxytocin. Examinations will be conducted at the end of one and two hours and uterine activity will be quantified. If after two hours no progress has occurred, patients on ambulation will be returned to bed and oxytocin utilized; patients on oxytocin will be given the option to ambulate. Length of labor, time from study entry to delivery, type of delivery, 1 and 5 minute Apgar scores, cord blood gases, maternal pain perception, newborn weight and neonatal problems will be noted.

PROGRESS: No subjects have been entered into this protocol as yet due to lack of time. Study will be started as soon as time permits.

Detail Summary Sheet

Date: 30 Dec 81 Prot No: 26/80 Status: Terminated

TITLE: A Comparison Study of Different Concentrations of Cefamandole Nafate During Cesarean Section

Start Date:	1st Comp Date:
Principal Investigator: CPT Eugene G. Rudd, MC	Facility: Tripler Army Medical Center
Dept/Sec: Dept of Obstetrics and Gynecology	Associate Investigators:
Key Words: Cefamandole nafate	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $300.	Periodic Review Results: Terminate

OBJECTIVE: To compare the efficacy of intrauterine irrigation with cefamandole nafate versus parenterally administered cefamandole nafate during cesarean section in reducing the febrile morbidity and the incidence of endomyometritis and its resulting complications following cesarean section.

TECHNICAL APPROACH: This study was designed to compare intravenous antibiotics to intrauterine irrigation with antibiotic post-cesarean section.

PROGRESS: Terminated due to departure of principal investigator.

Detail Summary Sheet

Date: 18 Jan 82	Prot No: 10/81	Status: Completed

TITLE: Retrospective Study of Conization Followed by Hysterectomy for Various Stages of Dysplasia

Start Date: Jan 81	Est Comp Date:
Principal Investigator: MAJ Clayton L. Shaw, MC, USAF	Facility: Tripler Army Medical Center
Dept/Sec: Obstetrics and Gynecology/Gynecology	Associate Investigators: LTC Heinz O. Osterholzer, MC COL Kunio Miyazawa, MC
Key Words: Dysplasia	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $500.	Periodic Review Results:

OBJECTIVE: (1) To clarify the need for reporting margin involvement in conization specimens and for follow-up histological examinations at the time of hysterectomy; and (2) to determine the incidence of persistent dysplasia in cones with negative and cones with positive margins.

TECHNICAL APPROACH: A review was made of the patients who underwent conization for dysplasia and CIS from January 1975 to July 1980, followed with a hysterectomy. This group of patients were studied by the following criteria:

CONE	HYSTERECTOMY
Age	Age
Date of surgery	Date of surgery
Depth of cone	Type of hysterectomy
Indication for cone	If BSO done
Pathology of cone	Cuff comments
Number of slides	Preoperative indications
ECC at surgery	Specimen gross description
Margins	Specimen pathology (residual tumor)

Depending on the size of the specimen, a minimum of 10 slides per specimen were reviewed.

PROGRESS: Charts and slides of 77 patients have been reviewed. A paper is in preparation.

Detail Summary Sheet

Date: 4 Jan 82 Prot No: 7177 Status: Ongoing
TITLE: Development of Clinical Assays

Start Date: Sep 77	1st Comp Date:
Principal Investigator: LTC Peter Angritt, MC	Facility: Tripler Army Medical Center
Dept/Sec: Dept of Pathology	Associate Investigators: CPT Willie Frazier, MSC John L. Claylaugh, M.S. COL Samuel P. Cucinell, MC COL James L. Hastings, MC
Key Words: Clinical assays	
Accumulative MEDCASE Cost:	1st Accumulative OMA Cost: $1500.
	Periodic Review Results: Continue

OBJECTIVES: This study is designed to (a) familiarize the clinical pathology resident with the field of new and developing assay kits; (b) give him an opportunity to evaluate the various assay kits for cost, effectiveness, and technique; and (c) determine which of the kits would be of greatest service to TAMC.

TECHNICAL APPROACH: All new laboratory tests which become available commercially will be evaluated by sending for information from the manufacturer. A number of kits will be purchased from various manufacturers. Clinical specimens will be obtained from patients with established diagnoses as well as from appropriate controls. Each kit will be compared for accuracy, sensitivity, ease of performance, cost, shelf life, etc. The investigator will estimate, based on current and future hospital requirements, which test (if any) is best.

PROGRESS: The Abbott Laboratories HBeAg kit will be evaluated next. As soon as evaluation is completed, a comprehensive serodiagnostic panel will be tested and compared to the current process to diagnose Hepatitis A, Hepatitis B and posttransfusional hepatitis (nonA-nonB). This panel will test for HBsAg, AntiHBc, Anti-HAV IgM, HBeAg, AntiHBe, and AntiHBs. A group of patients will be used to compare both methods of diagnosis and to establish which one is (a) faster, (b) more cost-effective (full panel vs. sequential ordering), and (c) more informative for follow-up purposes.

Detail Summary Sheet

Date: 18 Jan 82 Prot No: 22/16 Status: Ongoing
TITLE: Antidiuretic Hormone Secretion in the Asphyxiated Neonate

Start Date: Aug 80 Principal Investigator: CDR Edwin Bollerup, MC Dept/Sec: Dept of Pediatrics/Neonatology Key Words: Antidiuretic Hormone Asphyxiated neonate	Est Completion: Aug 82 Facility: Tripler Army Medical Center Associate Investigators: Jean L. Claybaugh, PhD
Accumulative Cost:	Est Accumulative O&M Cost $1000.
RELEASE Periodic Review Results, Continue	

OBJECTIVE: To evaluate and determine the physiologic response of antidiuretic hormone (ADH) secretion in cerebrospinal fluid (CSF) and plasma in the newborn infant who has experienced central nervous system (CNS) injury, hypoxemia and asphyxia, i.e., is there evidence for independent control of release of ADH into the CSF and plasma. Also, we intend to test the hypothesis that hypoxemia will increase the release of ADH into the CSF and consequently lead to increased pressure in the CSF or other evidence of cerebral edema.

TECHNICAL APPROACH: Subjects used for this study will be neonates admitted to the Special Care Nursery for evaluation of sepsis or possible sepsis. In addition, all newborn infants with intracranial hemorrhage, CNS injuries from birth trauma, and neonates experiencing severe asphyxia with hypoxemia, increased intracranial pressure, and cerebral edema. Asphyxia will be defined as follows: A 5 min Apgar score ≤6 and/or arterial blood pH ≤7.25 on admission to Special Care Nursery. On admission, each patient's APGAR scores, temperature, heart rate, blood pressure, and weight are recorded. Arterial blood gases are required for evaluation of acidosis, hypoxemia, and oxygen requirement. From each neonate, when possible, CSF opening pressure will be recorded, then 2 ml of spinal fluid will be collected and mixed with 0.1 ml of 1.0 N HCl/ml of CSF and immediately frozen for ADH assay. In addition, 5 ml of blood will be placed in a heparinized tube and plasma preserved with 0.1 ml of 1.0 N HCl/ml and frozen for ADH assay. Plasma and CSF will also be evaluated for Na^+ and K^+ concentration and osmolality. The data collected will be assessed to determine the correlation of CSF ADH

[illegible] and the correlations [illegible] of these factors to [illegible] stimulators of ADH release, i.e., plasma osmolality, [illegible] quality, body temperature, and arterial blood pressure and [illegible]. These data will be analyzed by multiple regression analysis to determine which factors most influence the independent release patterns of ADH into either the plasma or CSF. If computerized axial tomography scans are performed, an attempt will be made to correlate cerebral edema with high CSF ADH levels. It is anticipated that about 100 patients would provide sufficient information regarding the above-mentioned correlations.

PROGRESS: Project is ongoing and still active; initial data continues to be collected. Data to the present time is now being analyzed. To date, 22 neonates have been assessed for CSF ADH concentration. Of these, 20 have had sufficient blood gas analysis for preliminary statistical work-ups. None of the following results are as yet statistically significant, although expected tendencies are evident.

	Slope	r
Increased $\downarrow_{pH} \rightarrow \uparrow CSF_{[ADH]}$	-13.93	0.30
Increased APGAR @ 3 min $\rightarrow \uparrow CSF_{[ADH]}$	-[illegible].62	0.[illegible]5
Increased APGAR @ 10 min $\rightarrow \uparrow CSF_{[ADH]}$	-1.03	0.[illegible]3
Increased $PO_2 \rightarrow \uparrow CSF_{[ADH]}$	-0.02	0.[illegible]3
Increased $PCO_2 \rightarrow \uparrow CSF_{[ADH]}$	-0.03	0.00

Additionally, 13 neonates have been assessed for six 4-hour sequential urine samples postpartum, some of whom also had CSF ADH determinations. Correlations between CSF and/or urinary ADH with PaO_2, $PaCO_2$, pH, base excess, body temperature, systolic blood pressure, and APGAR scores, are presently underway. We have had difficulty getting the enthusiastic support that we need from the Department of Pediatrics in order to continue this project. We would like to emphasize the measurement of plasma [ADH] along with CSF [ADH] in future observations. It is expected that 40 to 60 more patients would be sufficient to complete this study.

Detail Summary Sheet

Date: 14 Jan 82 Prot No:1279 Status: Ongoing
Title: Intubation and Chest Tube Placement in Small Laboratory Animals

Start Date: Jul 79
Principal Investigator
CPT Jose Garcia, MC
Dept/Sec:
Dept of Pediatrics/Neonatology
Key Words:
Endotracheal intubation

1st Comp. at this Fac.
Facility:
Tripler Army Medical Center
Associate Investigators:

Accumulative MILPERS Cost.
1st Accumulative OMA Cost: $1500.
Pericic
Review Results: Continue

OBJECTIVES: To provide a teaching model for medical trainees in the proper techniques of endotracheal intubation and chest tube insertion.

TECHNICAL APPROACH: Young kittens and rabbits housed at the Tripler Army Medical Center Animal Facility will serve as animal models. The anatomy of the thorax and airway closely approximates that of the premature human infant. Standard intubation and thoracotomy equipment will be set up on a weekly basis at a time prearranged with Clinical Investigation Service and the Newborn Medicine Service. One of the above-named investigators will accompany 1-2 junior house staff officers to the facility and provide instruction in proper technique. Each house staff officer will then use the animal models to refine his own abilities.

PROGRESS: Training program continues unchanged. The above program was used in instructing all pediatric interns and some obstetrical interns during June and July 1981.

Detail Summary Sheet

Date: 15 Jan 82	Prot No: SWOG 7612	Status: Ongoing

TITLE: Comparison of Involved Field (IF) Radiotherapy and MOPP + Low Bleomycin with IF Radiotherapy and A-COPP in Stage III Hodgkin's Disease

Start Date: Aug 81	Est Comp Date:
Principal Investigator: COL David A. Maybee, MC	Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Hematology-Oncology	Associate Investigators: COL Constance P. Hastings, MC
Key Words: Hodgkin's disease, stage III	

Accumulative PEDCASE Cost:	Est Accumulative OMA Cost: $300.	Periodic Review Results: Continue

OBJECTIVE: To determine the effectiveness of a five chemotherapy drug and radiation therapy treatment on stage III Hodgkin's disease and to determine which of the five chemotherapy drug combinations gives the best results with the least side effects.

TECHNICAL APPROACH: Children diagnosed as having Stage III Hodgkin's disease are eligible.
Treatment will be as outlined in the study protocol.

PROGRESS: No patients have been entered into this protocol as yet.

Detail Summary Sheet

Date: 15 Jan 82 Prot No: SWOG 7617 Status: Terminated
TITLE: Combination Chemotherapy with Vinblastine Sulfate and Bleomycin Infusion in Children with Metastatic Solid Tumors (Phase II)

Start Date: Aug 81	Est Comp Date:
Principal Investigator: COL David A. Maybee, MC	Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Hematology-Oncology	Associate Investigators: COL Constance F. Hastings, MC
Key Words: Hodgkin's disease Germ cell carcinoma Histiocytosis	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $300.	Periodic Review Results: Terminate

OBJECTIVE: To determine the effects of this combination of chemotherapy on recurrent or metastatic solid tumors.

TECHNICAL APPROACH: Patient eligibility will be limited to patients with Hodgkin's disease, germ cell carcinoma, and histiocytosis.

Treatment will be as outlined in the study protocol.

PROGRESS: [illegible] patients registered. This protocol is now closed to new registrants.

Detail Summary Sheet

Date: 15 Jan 82 Prot No: SWOG 7621 Status: Terminated

TITLE: MOPP versus OPP in the Treatment of Children with Recurrent Brain Tumors (Phase III)

Start Date: Aug 81	Est Comp Date:
Principal Investigator: COL David A. Maybee, MC	Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Hematology-Oncology	Associate Investigators: COL Constance F. Hastings, MC
Key Words: Brain tumor, recurrent	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $300.
	Periodic Review Results: [illegible]

OBJECTIVE: To determine the effect of the combination chemotherapy on brain tumor and to determine whether eliminating the nitrogen from the MOPP combination will be as effective as the MOPP combination but with possibly less side effects.

TECHNICAL APPROACH: Children with brain tumor not responding to standard treatment will be eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: No patients have been registered. Protocol was closed to patient entry on 29 Oct 81.

Detail Summary Sheet

Date: 15 Jan 82	Prot No: SWOG 7623	Status: Completed

TITLE: Evaluation of Systemic Regimens in the Treatment of Acute Leukemia of Childhood, Phase III

Start Date: Aug 81		Est Comp Date:
Principal Investigator: COL David A. Maybee, MC		Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Hematology-Oncology		Associate Investigators: COL Constance F. Hastings, MC
Key Words: Leukemia, acute, childhood		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $300.	Periodic Review Results.

OBJECTIVE: To determine the effect of intensive, multidrug chemotherapy on acute lymphocytic leukemia and to determine whether treating with an antibiotic called trimethoprim-sulfa (Bactrim, Septra) helps to prevent infection during treatment for acute lymphocytic leukemia.

TECHNICAL APPROACH: Patients under 21 years of age at time of diagnosis of ALL, ASL, or AUL, with no previous therapy except for one week or less of corticosteroids prior to admission, falling into a good or poor prognosis category and having either no markers or T-cell markers, are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: Nine patients have been registered. This protocol is now closed to new entrants due to sufficient patient accrual.

Detail Summary Sheet

Date: 15 Jan 82	Prot No: SWOG 7660	Status: Completed
TITLE: Comparison of Involved Field Radiotherapy with Adjuvant MOPP Chemotherapy in the Treatment of Stage I and II Hodgkin's disease, Phase III		
Start Date: Aug 81		Est Comp Date:
Principal Investigator: COL David A. Maybee, MC		Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Hematology-Oncology		Associate Investigators: COL Constance F. Hastings, MC
Key Words: Hodgkin's disease, Stage I and II		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $300.	Periodic Review Results:

OBJECTIVE: To compare two forms of treatment for stage I and stage II Hodgkin's disease.

TECHNICAL APPROACH: Children 18 and under with untreated stage I and II Hodgkin's disease are eligible. Patients with massive mediastinal disease requiring local radiotherapy on an urgent basis for tumor shrinkage prior to lymphography and administration of anesthesia for staging celiotomy are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: Two patients have been registered in this protocol. The protocol is now closed to new entrants due to sufficient patient accrual.

Detail Summary Sheet

Date: 15 Jan 82	Prot No: SWOG 7712	Status: Ongoing

TITLE: Comparison of Treatment Regimens for First CNS Relapse in Childhood Acute Lymphoblastic Leukemia (CNS Leukemia Study #6), Phase III

Start Date: Aug 81	Est Comp Date:
Principal Investigator: COL David A. Maybee, MC	Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Hematology-Oncology	Associate Investigators: COL Constance P. Hastings, MC
Key Words: Leukemia, lymphoblastic, acute	

Accumulative MEDCASE Cost:	Est Accumulative UMA Cost: $300.	Periodic Review Results: Continue

OBJECTIVE: To determine whether, after a course of six treatments of three chemotherapy drugs given into the spinal fluid, radiation to the head and spinal column followed by no further treatment is better than radiation to the head alone followed by continuing courses of the three drugs into the spinal fluid.

TECHNICAL APPROACH: Children with acute lymphoblastic leukemia which has recurred in the central nervous system are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: No patients have been entered into this protocol as yet.

Detail Summary Sheet

Date: 15 Jan 82 Prot No: SWOG 7721 Status: Completed	
TITLE: Evaluation of Induction, Maintenance with and without Periodic Reinforcement, and CNS Prophylaxis in Acute Non-lymphocytic Leukemia	
Start Date: Aug 81	Est Comp Date:
Principal Investigator: COL David A. Maybee, MC	Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Hematology-Oncology	Associate Investigators: COL Constance F. Hastines, MC
Key Words: Leukemia, nonlymphocytic, acute	
Accumulative PTS/CASE Cost:	Est Accumulative OMA Cost. $300.
	Periodic Review Results:

OBJECTIVE: To try to cause a remission, to try to prevent metastases to the central nervous system, and to try to prolong the remission as long as possible.

TECHNICAL APPROACH: Patients under 21 years of age with diagnosis of acute myelocytic leukemia or acute myelomonocytic leukemia are eligible. Patients with a diagnosis of chronic granulocytic leukemia in blastic crises, erythroleukemia, or other rare forms of myelocytic leukemias are eligible, but will not be randomized. Patients must have had no previous therapy except one week or less of corticosteroids prior to admission. Patients must be available for periodic follow-up.

Treatment will be as outlined in the study protocol.

PROGRESS: Three patients have been registered. The protocol is now closed to patient entry due to sufficient patient accrual.

Detail Summary Sheet

Date: 15 Jan 82 Prot No: SWOG 7810 Status: Terminated

TITLE: Evaluation of Anguidine in Children with Acute Leukemia in Relapse, Phase II

Start Date: Aug 81	Est Comp Date:
Principal Investigator: COL David A. Maybee, MC	Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Hematology-Oncology	Associate Investigators: COL Constance P. Hastings, MC
Key Words: Lymphoid malignancy	
Accumulative PHOSA Cost:	First Accumulative FOMA Cost: $300.
	Periodic Review Results: [illegible]

OBJECTIVE: To determine the effect of anguidine on lymphoid malignancy.

TECHNICAL APPROACH: Children having lymphoid malignancy, disseminated in relapse, previously diagnosed as acute leukemia or lymphoma, who are not eligible for protocols of higher priority and who are resistant to standard forms of therapy are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: No patients have been registered. This study is now closed due to slow accrual of patients.

Detail Summary Sheet

Date: 15 Jan 82 Prot No: SWOG 7811 Status: Ongoing

TITLE: Evaluation of Anguidine in the Treatment of Central Nervous System Tumors (Phase II)

Start Date: Aug 81	Est Comp Date:
Principal Investigator: COL David A. Maybee, MC	Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Hematology-Oncology	Associate Investigators: COL Constance P. Hastings, MC
Key Words: Central nervous system tumors	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $300.	Periodic Review Results: Continue

OBJECTIVE: To determine the effect of anguidine on brain or spinal cord tumor.

TECHNICAL APPROACH: Children with malignant tumor of the brain or spinal cord that has not responded to therapy or for which there is no standard therapy are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: No patients registered as yet.

Detail Summary Sheet

Date: 15 Jan 82	Prot No: SWOG 7818	Status: Ongoing

TITLE: Evaluation of Rubidazone in Children with Acute Leukemia in Relapse, Phase II

Start Date: Aug 81		Est Comp Date:
Principal Investigator: COL David A. Maybee, MC		Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Hematology-Oncology		Associate Investigators: COL Constance F. Hastings, MC
Key Words: Leukemia		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $300.	Periodic Review Results: Continue

OBJECTIVE: To determine the effect of rubidazone on leukemia.

TECHNICAL APPROACH: Children with acute leukemia not responding to standard forms of therapy are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: No patients have been entered into this protocol as yet.

Detail Summary Sheet

Date: 15 Jan 82 Prot No: SWOG 7629 Status: Terminated
TITLE: Comparison of Two Dose Regimens of Intrathecal Methotrexate for CNS Leukemia, Phase II

Start Date: Aug 81	Est Comp Date:
Principal Investigator:	Facility:
COL David A. Mayber, MC	Tripler Army Medical Center
Dept/Sec:	Associate Investigators:
Pediatrics/Hematology-Oncology	COL Constance F. Hastings, MC
Key Words:	
Leukemia, CNS	

Accumulative MEDCASE Cost:	Est Accumulative CDMA Cost: $300.	Periodic Review Results: [illegible]

OBJECTIVE: To determine whether a lower dose of methotrexate given into the spinal fluid is more effective than the larger standard dose in treating central nervous system leukemia.

CLINICAL APPROACH: Children with leukemia in the central nervous system that recurs in spite of previous treatment are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: No patients registered. Protocol closed to accruals as of 27 Oct 81.

Detail Summary Sheet

Date: 15 Jan 82 Prot No: SWOG 7234 Status: Ongoing

TITLE: Second Induction and Maintenance in Acute Lymphocytic Leukemia (Phase III)

Start Date: Aug 81	Est Comp Date:
Principal Investigator: LTC David A. Maybee, MC	Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Hematology-Oncology	Associate Investigators: COL Constance F. Eastin, MC
Key Words: Leukemia, lymphocytic, acute	
Accumulative PEDC/SI Cost:	Est Accumulative OMA Cost: $300.
	Periodic Review Results: Continue

OBJECTIVE: To try to cause a remission, to try to prevent the spread of the leukemia to the central nervous system, and to try to prolong the remission as long as possible.

METHODICAL APPROACH: Patients must be under 21 years of age. Patients having received prior treatment with adriamycin, daunorycin, 6-TG, or systemic cytosine arabinoside are ineligible. Patients having had a previously treated relapse (CNS, BMD) are ineligible. For patients in their first CNS relapse, concurrent registration to SWOG 7712 is required. Patients with BMD are eligible; concurrent registration to the BMD protocol is required if patient qualifies. Patients with a combination of initial CNS and/or BMD relapse are eligible. Patients with CNS and/or BMD at initial diagnosis and previously treated are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: Two patients have been registered.

Detail Summary Sheet

Date: 15 Jan 82 Prot No: SWOG 7837 Status: Ongoing

TITLE: Evaluation of Systemic Therapy for Children with T Cell Acute Lymphatic Leukemia, Phase II

Start Date: Aug 81	Est Comp Date:
Principal Investigator:	Facility:
COL Pavic A. Maybee, MC	Tripler Army Medical Center
Dept/Sec:	Associate Investigators:
Pediatrics/Hematology-Oncology	COL Constance F. Hastings, MC
Key Words:	
Leukemia, T-cell	
Accumulative PTDCASL Cost:	Est Accumulative OMA Cost: $200.
	Periodic Review Results: Continue

OBJECTIVE: To determine the effectiveness of aggressive treatment of T-cell acute lymphatic leukemia and to determine which of two protocols is most effective with the least amount of side effects.

METHODOLOGY/APPROACH: Children with T-cell leukemia are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: No patients have been entered into the protocol as yet.

Detail Summary Sheet

Date: 15 Jan 82 Prot [illegible] Status: Ongoing
Title: Rescue Therapy for Non-CNS Extramedullary Disease in Children With Acute Lymphoblastic Leukemia, Phase III

Start Date: Aug 81	Est Completion:
Principal Investigator:	Facility:
COL David A. Maybee, MC	Tripler Army Medical Center
Dept/Sec:	Associate Investigators:
Pediatrics/Hematology-Oncology	COL Constance [illegible], MC
Key Words:	
Leukemia, acute lymphoblastic	
Accumulative RELEASE Cost:	Est Accumulative OMA Cost: $300.
	Periodic Review Results: Continue

OBJECTIVE: To determine the effectiveness of radiation therapy in controlling acute lymphoblastic leukemia outside of the bone marrow and outside of the central nervous system.

TECHNICAL APPROACH: Children with acute lymphoblastic leukemia recurring outside of the bone marrow and outside the central nervous system are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: [illegible]

Detail Summary Sheet

Date: 15 Jan [illegible] Prot # [illegible] Status: Ongoing
TITLE: V-COP Plus for Non-Hodgkin's Lymphoma in Children, [illegible]

Start Date: Age of Principal Investigator: CPT David A. Poyton, MC Dept/Sec: Pediatrics/Hematology-Oncology Key Words: Lymphoma, non-Hodgkin's	Dr. Comp for Facility: Tripler Army Medical Center Associate Investigators: COL Constance F. Hastings, MC

Accumulative MEDCASE Cost:	1st Accumulative OMA Cost: $300.	Periodic Review Results: Continue

OBJECTIVE: To determine the effect of the combination of chemotherapy and radiation therapy on non-Hodgkin's lymphoma and to determine which of two protocols is more effective with the least side effects.

TECHNICAL APPROACH: Children with non-Hodgkin's lymphoma are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: [illegible] patient has been registered.

Date: 15 Jan 82 Prot No: SWOG 7961 Status: Terminated
Title: Multidrug Adjuvant Chemotherapy in Nonmetastatic Osteosarcoma:
Comparison of CONPADRI-I with CONPADRI-V (Phase III)

Start Date: Aug 81	Est Comp Date:
Principal Investigator: COL David A. Maybee, MC	Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Hematology-Oncology	Associate Investigators: COL Constance F. Hastings, MC
Key Words: Osteosarcoma, nonmetastatic	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $300.	Periodic Review Results: Terminate

OBJECTIVE: To determine the effect of a combination of chemotherapy on osteosarcoma, to determine the effect of adding high-dose methotrexate to the combination of chemotherapy drugs in CONPADRI-I, and to determine which combination, CONPADRI-I or CONPADRI-V, is more effective in treating osteosarcoma.

MEDICAL APPROACH: Children with osteosarcoma.

Treatment will be as outlined in the study protocol.

PROGRESS: No patients have been registered. Protocol is now closed to patient entry.

Detail Summary Sheet

Date: 15 Jan 82 Prot No: SWOG 7919 Status: Ongoing

TITLE: Evaluation of m-AMSA in Children with Acute Leukemia and Non-Hodgkin's Lymphoma in Relapse, Phase II

Start Date: Aug 81	Est Comp Date:
Principal Investigator: COL David A. Maybee, MC	Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Hematology-Oncology	Associate Investigators: COL Constance P. Hastings, MC
Key Words: Leukemia Lymphoma, non-Hodgkin's	
Accumulative PTCASE Cost:	Est Accumulative ONA Cost: $300.
	Periodic Review Results: Continue

OBJECTIVE: To determine the effect of m-AMSA on acute leukemia or non-Hodgkin's lymphoma.

DESIGN/APPROACH: Children with acute lymphoblastic leukemia, acute non-lymphoblastic leukemia, or non-Hodgkin's lymphoma are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: No patients have been entered into this protocol as yet.

Detail Summary Sheet

Date: 15 Jan 82 Prot No: SWOG 7994 Status: Terminated

TITLE: Therapy for Extraocular Retinoblastoma with Cyclophosphamide, Vincristine, Adriamycin, and Irradiation

Start Date: Aug 81	Est Comp Date:
Principal Investigator: COL David A. Maybee, MC	Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Hematology-Oncology	Associate Investigators: COL Constance F. Hastings, MC
Key Words: Retinoblastoma	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $300.	Periodic Review Results:

OBJECTIVE: To determine the effectiveness of chemotherapy drugs in treating retinoblastoma and the effectiveness of combining radiation therapy and chemotherapy.

TECHNICAL APPROACH: Children with histologically proven extraocular retinoblastoma are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: This study was closed due to lack of patient accrual.

Detail Summary Sheet

Date: 15 Jan 82 Prot No: SWOG 8000 Status: Ongoing
TITLE: The National Wilms' Tumor Study III

Start Date: Aug 81	Est Comp Date:
Principal Investigator: LCL David A. Maybee, MC	Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Hematology-Oncology	Associate Investigators: LCL Constance F. Mastiros, MC
Key Words: Wilms' tumor	
Accumulative Patients to Date:	1st Accumulative DMA Cost: $300.
	Periodic Review Results: Continue

OBJECTIVE: To determine the effect of chemotherapy on Wilms' tumor and to determine which chemotherapy schedule is best. This study is also designed to determine if radiation therapy is necessary when the tumor has been completely removed and in what dosage.

CLINICAL APPROACH: Children diagnosed as having Wilms' tumor are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: Two patients have been registered.

Detail Summary Sheet

Date: 15 Jan 82 Prot No SWOG 8011 Status: Ongoing

TITLE: PCNU in Recurrent Childhood Medulloblastoma and Ependymoma, Phase II

Start Date: Aug 81	Est Comp Date:
Principal Investigator: COL David A. Maybee, MC	Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Hematology-Oncology	Associate Investigators: COL Constance F. Hastings, MC
Key Words: Medulloblastoma Ependymoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $300.
	Periodic Review Results: Continue

OBJECTIVE: To determine the effectiveness of the chemotherapy drug PCNU on medulloblastoma and ependymoma recurring after previous therapy.

TECHNICAL APPROACH: Children with medulloblastoma or ependymoma recurring following therapy are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: 0 patients have been entered into this protocol as yet.

Detail Summary Sheet

Date: 15 Jan 82 Prot No: SWOG 8011 Status: Ongoing
Title: Evaluation of m-AMSA in Children with Solid Tumors, Phase II

Start Date: Aug 81	1st Comp Date:
Principal Investigator: (C) David A. Mayhee, MC	Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Hematology-Oncology	Associate Investigators: COL Constance F. Hastings, MC
Key Words: Solid tumor	
Accumulative Patients: 0	1st Accumulative CPA Cost: $300.
	Periodic Review Results: Continue

OBJECTIVE: To determine the effectiveness, if any, of the investigational drug m-AMSA on solic tumor recurring after previous treatment.

CLINICAL APPROACH: All patients with solid tumors in relapse who are 21 years of age or younger at the time of diagnosis, who are not eligible for protocols of higher priority and who are resistant to standard forms of therapy, will be eligible. Patients must have measurable tumor and a life expectancy of at least 4 weeks. Patients must have an AGC of >500/mm³ and platelet count >100,000/mm³, unless patient has evidence of tumor invasion of the bone marrow. Normal renal (BUN <20 and creatinine <1.2 mg/dl) and liver function tests pretherapy (bilirubin <2 mg/dl) and normal serum potassium are required for all patients. Patients may have received no prior therapy with m-AMSA.

Treatment will be as outlined in the study protocol.

RESULTS: No patients have been entered into this protocol as yet.

Detail Summary Sheet

Date: 15 Jan 82	Prot No: SWOG 8022	Status: Ongoing
TITLE: Evaluation of Vindesine Twice Weekly Plus Prednisone and a Cross-over Study of Vindesine-Prednisone vs Vincristine Prednisone in Children with Acute Lymphoblastic Leukemia, Hodgkin's Disease, and Non-Hodgkin's Lymphoma, Phase II-III		
Start Date: Aug 81		Est Comp Date:
Principal Investigator: COL David A. Paybee, MC		Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Hematology-Oncology		Associate Investigators: COL Constance L. Hastings, MC
Key Words: Leukemia, acute lymphoblastic Hodgkin's disease Lymphoma, non-Hodgkin's		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $300.	Periodic Review Results: Continue

OBJECTIVE: To compare the effectiveness of vindesine plus prednisone to the standard therapy of vincristine plus prednisone for the treatment of acute lymphoblastic leukemia, Hodgkin's disease, and non-Hodgkin's lymphoma.

TECHNICAL APPROACH: Children with acute lymphoblastic leukemia, Hodgkin's disease, and non-Hodgkin's lymphoma recurring on therapy and not shown to be resistant to vincristine and prednisone are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: No patients have been entered into this protocol as yet.

Detail Summary Sheet

Date: 15 Jan 8[illegible]
TITLE: A Study of the Association of HL Antigen Phenotype, Karyotype
to Malignant Disease and Subsequent Survival Benefit

Start Date: Aug 81	Status:
Principal Investigator:	Terry:
CDR David A. Bayless, MC	Project Officer:
Dept/Sec:	Associate Investigators:
Pediatrics/Hematology-Oncology	CDR Constance F. Hermiz, MC
Key Words:	
Allergies	
Bacteria, Lymphocytic, acute	
Neuroblastoma	

Accumulative PEDC/SI Cost:	1st Accumulative CMA Cost: $300.	Periodic Review Results: Continue

OBJECTIVE: To look at how cancer might be passed on in the genes.

TECHNICAL APPROACH: All newly diagnosed patients with ALL (Black only) or neuroblastoma (white only) 15 years of age and under are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: No patients have been entered into the study as yet.

Detail Summary Sheet

Date: 15 Jan 82 Prot No: SWOG 7695 Status: Ongoing

TITLE: Multimodal Therapy of Metastatic Ewing's Sarcoma With Chemotherapy Plus Irradiation and Surgery (if Feasible), Intergroup, Phase III

Start Date: Aug 81	Est Comp Date:
Principal Investigator: COL David A. Mayhee, MC	Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Hematology-Oncology	Associate Investigators: COL Constance F. Hastings, MC
Key Words: Ewing's sarcoma	
Accumulative MEDCASE Cost:	Est Accumulative UMA Cost: $300.
	Periodic Review Results: Continue

OBJECTIVE: To determine the effectiveness of an intensive 5-drug chemotherapy plan using Adriamycin, vincristine, cyclophosphamide, 5-fluorouracil, and actinomycin-D plus radiation therapy and surgery in metastatic Ewing's sarcoma.

CLINICAL APPROACH: Children with metastatic Ewing's sarcoma are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: No patients have been entered into this protocol as yet.

Project Summary Sheet

Date: [illegible] Prot No: [illegible] Status: [illegible]
Title: Interaction of Depressed Mood and Cognition as [illegible]
[illegible]

[illegible]
[illegible]
[illegible]
[illegible]
[illegible]
[illegible]

[illegible]
[illegible]
[illegible]
[illegible]
[illegible]
[illegible]

Accumulative [illegible] List: Accumulative Statistic
Cost: UA Cost: $300. Review Results: Continue

OBJECTIVES: As part of a larger program of research, it is proposed to use a retrospective chart study method to compare the decrement in cognition associated with depression in two age groups. Patients with a diagnosis of depression who are over 60 will be compared to patients with a similar diagnosis who are under 30. We specifically hypothesize a greater right hemisphere decrement in cognition as a function of depressed mood in the older group of patients.

TECHNICAL APPROACH: We plan to select all cases of patients with a diagnosis of depression in the last three years for whom intelligence testing was done, and who are either over 60 or under 30. Using the charts and psychological evaluations of these patients, we will construct an index to rate the severity of each patient's depression. Using this index, patients within each age group will be subdivided into severe or moderate depression groups. The subtest scores of each group will then be compared to the age-related norms that are published for each subtest. We will also form comparable groups made up of age-matched schizophrenic patients as comparison samples. The scores of each age group will also be compared to each other. Standard statistical techniques will be used to analyze the data.

PROGRESS: This project currently awaits a list of names requested from Patient Administration Division.

Date: 5 Jan 82 Prot No: 4781 Status: Completed

Title: The Military Child Psychiatry Outpatient Population: A Study of Demographics, Referral Patterns, and Diagnosis

Start Date: Nov 80	Est Comp Date:
Principal Investigator: CPT Stephen M. Schilt, MC	Facility: Tripler Army Medical Center
Dept/Sec: Dept of Psychiatry	Associate Investigators:
Key Words:	

Cumulative MEDCASE Cost:	1st Accumulative OMA Cost: $1000.	Periodic Review Dates:

OBJECTIVES: The purpose of this study is to assess demographic variables, referral patterns, and diagnostic categories of the clinic population.

METHODOLOGY: We reviewed and coded the charts of [illegible] patients seen in the Child Psychiatry Outpatient Clinic from [illegible] 1980. Information was obtained from standard intake forms completed by the patients' parents at the time of evaluation. Data on the following variables was compiled: age, sex, family constellation, ethnic background, educational status, previous psychiatric treatment, referral source, presenting symptoms, and final DSM III diagnosis of the child; parent's marital status, socioeconomic level, religion, and military status. The statistics compiled were compared to the statistics available on the military population of Hawaii.

PROGRESS. The data of this report indicate that the incidence of child psychiatry referrals among Hawaii's military population differs little from the incidence reported by similar civilian clinics. The parenting situation was similar to the civilian community and was somewhat more stable than that reported by civilian clinics. The incidence of referral for each branch of service was quite similar, suggesting that inter-service differences in military stresses do not play a role in child psychiatry referrals. The similarity between CHAMPUS and military clinic cases indicated that neither facility was servicing a sector of the military population distinct from the other. One must question whether the perpetuation and escalation of this duplication of services is the most cost-effective way of providing optimum child psychiatry services for the military. The economic and therapeutic issues are of such magnitude that this matter clearly warrants further investigation. A manuscript is in preparation.

Date: 30 Dec 81 Protocol: 2/81 Status: Ongoing

Title: Adolescent Obesity: A Behavioral Treatment Program Emphasizing Exercise.

Principal Investigator:	Facility:
David S. Weiss, Ph.D.	Trigler Army Medical Center
Office:	Associate Investigators:
Psychiatry/Child Adolescent Psychiatry	LTC David L. Suttle, MC
Key Words:	MAJ Layne Hill, MC
Obesity	CPT Walter L. Charles, MSC
	CPT Linda L. Fischer, MSC

Cumulative Hours for Cumulative Periods:	
Open Test: 300.	Review Interval: Continue

Objectives: To investigate the effects of a behavior modification program emphasizing exercise on body weight and fat reduction, on weight and fat loss maintenance, and on physical fitness in obese adolescents.

Research Approach: The project is structured to test two variables (treatment versus control; eating habits + exercise). Groups include (1) traditional diet control, (2) eating habits alone, (3) exercise alone, and (4) combined eating habits and exercise. Participants meet for twenty-one sessions over a six-month period.

Progress: Participants have not yet begun treatment as we are awaiting the necessary equipment.

[illegible]

Date: 15 Jan 7[illegible] Prot No: 18/7[illegible] [illegible]

TITLE:

Clinical Evaluation of Ci[illegible] [illegible]

[illegible]

Start Date: [illegible]

Principal Investigator: [illegible]

MAJ Peter F. Clarke, MC [illegible]

Dept of Radiology/Nuclear Medicine

Key Words:

Cisternogram

Indium-111 DTPA

Accumulative MEDCASE: [illegible] Est Accumulative [illegible] Periodic [illegible]

Cost: [illegible] OMA Cost: $1,0[illegible] Review Results: [illegible]

OBJECTIVES: Since there is currently a moratorium on the use of [illegible] cisternography, it is our purpose to substitute Indium-111 DTPA for [illegible] in this procedure. Indium-111 DTPA (Diethylene Triamine Penta Acetic Acid) is presently in the third phase of investigation [illegible] FDA. The agent will be used for the following: (1) Detection of [illegible] cating hydrocephalus; (2) Detection of noncommunicating [illegible]; (3) Aid in determining whether a cerebrospinal fluid shunt [illegible] required; (4) Detection of rhinorrhea; and (5) Study of [illegible] fluid dynamics.

TECHNICAL APPROACH: Radionuclide cisternography will be performed utilizing Indium-111 DTPA in those patients with the above-described medical problems. Results obtained from these procedures will [illegible] compared with results obtained with earlier [illegible] cisternography [illegible] results obtained by other laboratories. The results will be correlated with the results of clinical findings, by roentgenographic studies [illegible] autopsy of surgical material where available to determine the accuracy and limitations of this procedure in each of the categories [illegible] studied. Approximately [illegible] of Indium-111 DTPA will be [illegible] intrathecal or intraventricular injection to patients referred to the Nuclear Medicine Laboratory for scintigraphic evaluation of [illegible] spinal fluid pathways. The patients will meet the following criteria: (1) nonpregnant and over the age of [illegible] years unless special indications for study exist; (2) all will have either known or suspected alterations of cerebrospinal fluid flow. No subject without manifest or suspected disease will be studied.

PROGRESS: Cisternography was performed on [illegible] patients during FY [illegible]. The study has proved to be a useful adjunct in assessing the cerebrospinal fluid dynamics of all patients.

AD-A110 784 TRIPLER ARMY MEDICAL CENTER HI F/G 6/5
CLINICAL INVESTIGATION PROGRAM.(U)
OCT 81 S A CUCINELL

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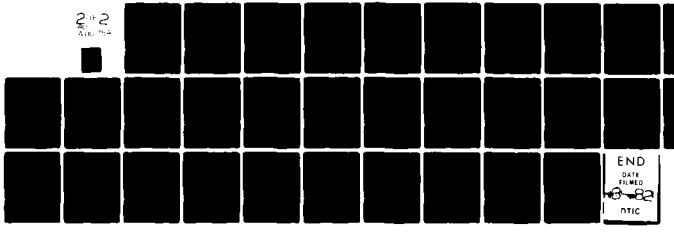

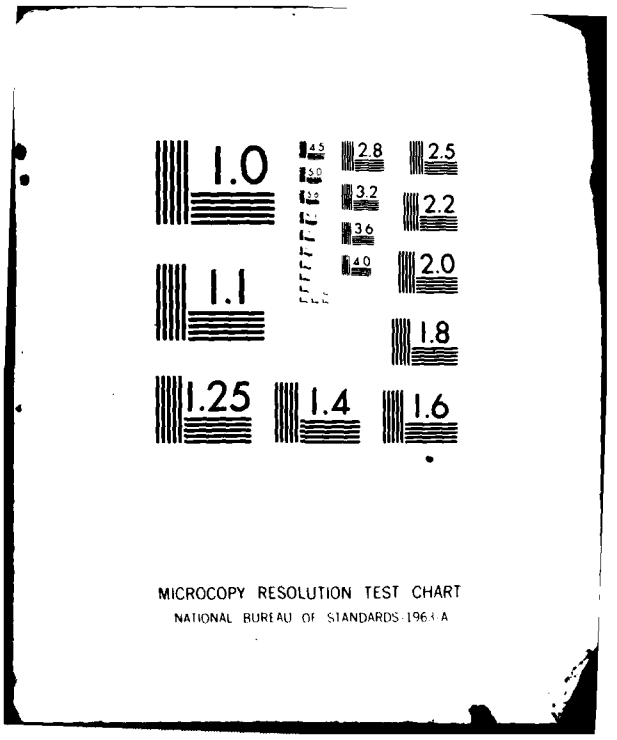
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MICROCOPY RESOLUTION TEST CHART
NATIONAL BUREAU OF STANDARDS-1963-A

Detail Summary Sheet

Date: 5 Jan 76 Prot No: 21/76 Status: Ongoing
Title: Clinical Evaluation of Fluorescent Scanning of the Body w/ with Technetium-99

Start Date: 1 Jul 76
Principal Investigator:
Maj Anna K. Thecio, MC
Dept/Sec:
Dept of Radiology, Nuclear Medicine Sec
Key Words:
Fluorescent Scanning
Thyroid

Est Comp Date:
Facility:
Tripler Army Medical Center
Associate Investigators:

Cumulative No. of Pts: 1st Cumulative Periodic
Est: 30,000 Act: 25,000 Review: Results Continue

OBJECTIVE: To determine the value of fluorescent thyroid imaging as compared with other modalities of thyroid imaging in the diagnosis and evaluation of the severity of thyroid abnormalities.

APPROACH: Dual studies are intended to involve both conventional thyroid scanning and fluorescent technique scanning in patients studied in the thyroid clinic at TAMC.

PROGRESS: No fluorescent scans were performed during FY 76, due to staff shortages. When personnel shortages are resolved, the project will again be resumed.

Detail Summary Sheet

Date: 15 Jan 92 Prot No: 1900 Status: Pending

Title: Study of the Internal Mammary Lymph Nodes in Patients with Inner Quadrant Breast Cancer

Cert Date:	Inst Comp Date:
Principal Investigator:	Facility:
Lee Anna L. Cracchi, LTC	Tripler Army Medical Center
Dept/Sec:	Associate Investigators:
Dept of Radiology/Nuclear Medicine	LTC Charles F. Miller, M
Comp:	LTC Marybeth [illegible]
Type of Cancer	CPT Howard [illegible]
Antimony sulfide colloid	[illegible]
	[illegible]
Cumulative Patient Accrual:	Last Accumulative
Cost:	OPA Cost Date:
	Previous Annual

OBJECTIVES: To determine if the presence or absence of malignancy in internal mammary nodes will make any difference in the morbidity or mortality of patients with breast cancer.

METHODOLOGICAL APPROACH: Patients studied will be women who have proven or highly suspected breast carcinoma. No pregnant or lactating women, or those under 18 years of age will be administered the drug. Only those patients in which the benefits to be gained by the study outweigh any risks to the patient as determined by the physician.

The antimony sulfide colloid will be obtained from the Union Carbide Corporation. Tagging will be performed locally with Tc-99m.

A 99m antimony sulfide colloid 500 μCi, will be injected into the posterior rectus sheath on the ipsilateral side. Two to one half to three hours later a camera will be utilized with a suitable collimator to image the internal mammary lymph nodes on the ipsilateral side.

PROGRESS: To date, approval for performing this study at Tripler has not been granted by the Surgeon General's Human Subjects Research Review Board. Therefore, no progress on this study has been made.

Retail Summary Sheet

Date: 15 Jan 82 Prot No. 20/80 Status: Ongoing
Title: In Vivo Evaluation of Hepatobiliary Systems with [illegible]

Start Date: Jan 82
Principal Investigator:
[illegible]
Dept/Sec:
Dept of Radiology/Nuclear Medicine
[illegible]
Hepatobiliary System

Tri-Service Participation
Facility:
Tripler Army Medical Center
Associate Investigators:

Accumulative Total Cost: 1st Accumulative Total Cost: $1666. Periodic Review: Quarterly

OBJECTIVE: To demonstrate the safety and efficacy of [illegible]-Choletec kit for the in vivo evaluation of hepatobiliary system in patients suspected of having hepatobiliary disease.

CLINICAL APPLICATION: The study will include patients suspected of having hepatobiliary disease which can include jaundice of any cause, acute pain in which cholecystitis is suspected, or suspected mass lesions of the liver from other clinical or diagnostic studies. No pregnant women, lactating women, or persons under 18 years of age will be administered the drug, unless the benefits gained outweigh the risks, in the opinion of the investigator. The HIDA will be obtained in kit form from Union Carbide. Labeling will be done in the Nuclear Medicine Service by experienced personnel. The suggested dose range employed in the average (70 kg) patient is 2-15 mCi [illegible] depending on the level of a recent serum bilirubin determination or clinical estimate of the degree of jaundice, if no serum bilirubin level is available.

PROGRESS: Hepatobiliary scans were performed on 14 patients during FY 81. The studies proved to be useful adjuncts in assessing hepatobiliary disease.

[illegible]

[illegible]	[illegible]
Principal Investigator:	Facility:
[illegible]	Tripler Army Medical Center
Dept/Sec:	Associate Investigators:
Dept of Radiology/Diagnostic Radiology	(If some levels)
[illegible]	
[illegible]	
Accumulative MEDCAS: 1st Accumulative	Periodic
Cost: OMA Cost: $ 00.	Review Results: [illegible]

OBJECTIVE: To study the size of the thoracic aorta by computed tomography in the normal and abnormal patient.

Accrual Ability: Many patients have computed tomography [illegible] for various reasons, such as looking for mass lesions. Utilizing these patients and patients referred to us for evaluation of the thoracic aorta, multiple measurements will be obtained in order to correlate their PA chest radiography with the computed tomographic images. We will look specifically at the difference between symptomatic and asymptomatic aortas.

Progress: Thus far we have been obtaining and putting [illegible] the computed tomographic images which will be recalled in the near future for evaluation and measurement, along with correlation with chest radiographs.

Detail Summary Sheet

Date: 22 Dec 81	Prot No: 15/80	Status: Terminated

TITLE: The National Study of Contrast Media Reactions

Start Date:	Est Complete:
Principal Investigator:	Facility:
COL Raoul O. Tagen, MC	Tripler Army Medical Center
Dept/Sec:	Associate Investigators:
Dept of Radiology	CPT Ronald L. Irby, MC
Key Words:	
Contrast Media	
Accumulative Pt Accrual: Est Accumulative Cost:	Periodic Review Required: Original

OBJECTIVE: To study the effects of premedication on the incidence of adverse contrast media reactions.

METHODOLOGICAL APPROACH: This is a randomized, double-blind study involving participating medical centers across the U.S.A. As many as 200,000 patients receiving IVPs may eventually be enrolled in this study. The patients will be assigned to one of four groups: (1) 32 mg of Medrol in the evening preceding urography and 32 mg of Medrol again in the morning at least 2 hours before the IVP is given. (2) 32 mg of Medrol in the morning at least 2 hours before the IVP is given. (3) Placebo in the evening preceding urography and again in the morning at least 2 hours before the IVP is given. (4) Placebo in the morning at least 2 hours before the IVP is given. The intravenous pyelogram will be carried out with the usual technique employed in each institution. Appropriate medications to treat reactions, if they occur, will be immediately available.

PROGRESS: Because of the long delay in obtaining approval and the problems with communication between San Diego and Honolulu, this study was terminated prior to starting. No patients were studied.

Detail Summary Sheet

Date: 13 Dec 80 Prot No: 3977 Status: Ongoing

Title: The Value of Gallium Scans in Determining Prosthetic Aortic Graft Infections in Canines

Start Date: Aug 76	1st Completion Date:
Principal Investigator: LTC Charles A. Andersen, MC	Facility: Tripler Army Medical Center
Dept/Sec: Dept of Surgery/Vascular Surgery	Associate Investigators: MAJ Anna L. Greco, MC; CPT Clayton L. Seifert, MC; CPT Carroll Ray Nelson, III
Key Words: Aortic graft infection, Gallium scans	
Cumulative MTF Acft Cost:	1st Accumulative O&M Costs: $3000.
Periodic Review Results: Continue	

Objectives: To determine the values of diagnostic aortic graft infection.

Approach: Prosthetic aortic grafts are placed in dogs. Some dogs are kept as control dogs or given a dose of E. coli bacterial colonies to infect the graft. After several months, the grafts are scanned with Gallium scans to determine whether the Gallium can accurately predict the presence of an infected graft. After an appropriate time, the animals are sacrificed and the grafts are examined grossly and histologically and bacteriologically for evidence of a graft infection.

Progress: There has been no progress made in the project since the last report. It was previously determined that more control studies were needed, and this is planned for the next fiscal year.

Detail Summary Sheet

Date: 30 Jan 81 Prot No: 11/16 Status: Completed
Title: [illegible] Counseling of Preoperative Patients

Start Date: Jan 80 Est Comp Date:
Principal Investigator: Facility:
LTC Charles A. Andersen, II Tripler Army Medical Center
Dept/Sec: Associate Investigators:
Dept of Surgery
Key Words:
Audiovisual counseling

Accumulative Cost:	PROJECT	Est Accumulative OMA Cost: $600.	Periodic Review Results:

Objective: To evaluate the effectiveness of an audiovisual tape, together with a verbatim transcript of the audio portion of the tape, in preparing patients for an operation.

Research Methods: All patients undergoing elective cholecystectomy will be counseled by the operating surgeon utilizing the format that they have previously used. In addition to the routine counseling, 50 percent of these surgeons' (randomly selected) patients will be shown a videotape on gallbladder surgery by a nurse who is not involved in their care. These patients will then be given a printed transcript of the tape. The nurse will have all cholecystectomy patients complete a questionnaire in regard to attitudes. After each patient in the study has been discharged, the nurse will review the chart and record pertinent data. All patients will be asked to complete a retrospective questionnaire.

The study is to be conducted as a joint project with the Peterson Army Hospital with physicians from several hospitals participating. The data will be collected, compiled, and stored for 18 months. At the conclusion of the study the data analysis will be conducted in two parts, requiring approximately [illegible] key-punching of the data with [illegible] computer dollars.

Progress: The clinical work has been completed at Tripler Army Medical Center, Straub Clinic, Queen's Medical Center, and Kaiser Hospital. The data is currently being analyzed by physicians and statisticians, and appropriate papers will be prepared.

Date: 23 Dec 81 Prot No: 0/77 Status: Ongoing
TITLE: Regrowth of Small Intestinal Mucosal Surface Area

Start Date: Nov 76	Est Completion: Sep 82
Principal Investigator: MAJ Peter J. Garcia, MC	Facility: Tripler Army Medical Center
Dept/Sec: Dept of Surgery/General Surgery	Associate Investigators: CPT Clayton L. Radich, MC
Key Words: Small intestinal mucosal surface regrowth	
Accumulative MILES: Test	Est Accumulative FTA (est. 5QFY):
Periodic Review Results Pending	

OBJECTIVE: To explore methods of increasing small intestinal mucosal absorptive area following massive resections, and to determine the technical feasibility and functional results of certain specific techniques.

BACKGROUND/RATIONALE: Based on previous successful studies in regrowth of mucosa with growth of neogut on the serosal surface of the colon, the next step will be to (1) perform similar studies in the pig (similar gastrointestinal tract and physiologic responses similar to man), and (2) attempt growth of neogut on the peritoneal surface of the abdominal wall. This would mirror the clinical circumstance if no suitable colonic recipient site were available. Five pigs will undergo laparotomy under general anesthesia and each animal will have two grafts placed. After varying periods of time (maximum 8-12 weeks) at a second procedure, these grafts could be harvested and intestinal continuity would be restored.

PROGRESS: An initial series of dogs has provided us with the following data: (1) A new small intestinal mucosa will grow across the serosa of the colon under these circumstances; and (2) the graft is mechanically functional, i.e., food is propelled in a relatively normal fashion through the graft, and these animals do not develop small intestinal obstruction. We have been unable to work on this project in FY 81. With increased staff, we hope to complete the study in FY 82.

This project won second prize in the Hawaii American College of Surgeons Annual Essay Contest, Honolulu, Hawaii, June 1977. Presented to the Gillies Beaumont Gastrointestinal Symposium, El Paso, Texas, March 1978.

Detail Survey Sheet

Date: 14 Jan 82	Prot No: 25/78	Status: Ongoing

TITLE:

Microvascular Training Protocol

Start Date: May 78	Est Comp Date: Indefinite
Principal Investigator: MC Strawford L. Fees, M.C. Dept/Sec: Dept of Surgery/Plastic Surgery Key Words: Training Microvascular	Facility: Tripler Army Medical Center Associate Investigators:

Accumulative Costs: Est Accumulative Cost: Period: Review Results: Date:

Objective: To develop and maintain microvascular surgical skills among the plastic surgery service staff. Also, are to train general surgery and other specialty residents with the techniques of microvascular anastomosis.

Clinical Applic: To divide and reanastomose the carotid artery and vena cava rats. One pair of vessels per week with histologic evaluation of patency is planned. Later expansion to other models such as the rabbit ear and dog intestine and vas deferens is possible.

PROGRESS: Until the arrival of a second plastic surgeon in June of 81 the clinic workload precluded weekly laboratory sessions. Since June the workload has lessened and the project will soon be continued on a regular basis.

Detail Summary Sheet

Date: 15 Jan 82 Prot No: 77/30 Status: Ongoing
Title: Patterns of Injury in Motorcycle Accidents

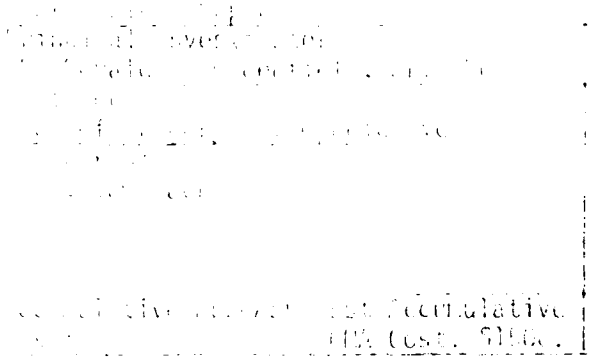
Start Date: Jul 80	Est Comp Date:
Principal Investigator: CPT Gerald Q. Greenfield, Jr., MC	Facility: Tripler Army Medical Center
Dept/Sec: Dept of Surgery/Orthopedic Svc	Associate Investigators:
Key Words: Injuries, Motorcycle	
Cumulative Proj Cost:	Est Accumulative Add'l Cost:	Periodic Review Cycle: Annual

OBJECTIVE: To define the circumstances surrounding motorcycle accidents and injuries.

METHODOLOGY: Accidents will be studied to determine the circumstances surrounding the accident with. This will include factors of motorcycle, and injury produced as well as long-term rehabilitation or duty limitation.

FINDINGS: This study comprises review of 300 patients admitted to hospital for injuries sustained in motorcycle accidents over a 5-year period. All patients were cared for by the surgical house staff of the operative procedures were performed by the house staff with attending staff supervision. Most of the patients were under 30 years old and lower extremity fractures occurred most frequently. Patients were hospitalized for an average of 6 weeks. An effort is being made to relate length of motorcycle ownership and riding experience to the potential for significant injury.

An abstract has been accepted for presentation at the Residents Conference, American Orthopaedic Association, Washington, DC, April 1982.



[illegible] of these two types of patients seen in the [illegible] will be studied. Also studied will be the cases [illegible] by the surgeon.

[illegible] questionnaire will be used to collect [illegible] clinical records of these patients will be reviewed [illegible] will be compared in a study [illegible] in the application of the special [illegible]

[illegible] for the person to [illegible] from the questionnaires selected. [illegible] events of the past. These were divided into four [illegible] sports or exercise, [illegible] social relationships of persons. [illegible], however, listed [illegible] recovery [illegible] of recovery [illegible] [illegible] physical therapy in the form of flexion exercises [illegible] number of recurrences.

[illegible] at the [illegible] meeting of the Society of Military [illegible] in San Antonio, TX, Nov 1980.

[illegible]

Title: Effect of [illegible] on [illegible] Chondromalacia Patella

Start Date: [illegible]
Principal Investigator: [illegible] Gerald C. Greenfield, [illegible]
Dept/Svc: Surgery/Orthopedics
Key Words: Chondromalacia

Est Completion Date: [illegible]
Facility: Tripler Army Medical Center
Associate Investigators: [illegible]

Accumulative MEDCASE: [illegible] | Est Accumulative OMA Cost: $[illegible] | Periodic Review Results: [illegible]

OBJECTIVE: To determine the effect of [illegible] on the course of chondromalacia.

TECHNICAL APPROACH: Patients to be included in the study [illegible] diagnosed as having chondromalacia patella by bone scan. [illegible] prior history of knee surgery will be excluded from the study. [illegible] clinical examination, plain roentgenographs and bone scan [illegible] patellar view will be obtained. Patients will [illegible] two groups. Both groups will be treated with [illegible] and begin a program of physical therapy. [illegible] placed on a standard program of quadriceps strengthening [illegible]. The second group will be placed on a program of [illegible] exercises with [illegible] contractions augmented by a [illegible]. Each group will be on a six-week regimen. At the end of the treatment period a second set of roentgenographs will be obtained. [illegible] those patients whose initial study was abnormal, a second bone scan [illegible] be performed.

PROGRESS: Data collection beginning. Plan to present [illegible] Military Orthopaedic Surgeons Meeting 1987 and to the American [illegible] of Orthopaedic Surgeons Meeting in 198[illegible].

Detail Summary Sheet

[illegible] Prot No: [illegible] Status: [illegible]
[illegible] Intraocular Implantation of Intraocular Lenses

[illegible] Principal Investigator [illegible]
[illegible]
[illegible]

[illegible] cumulative [illegible] Periodic
[illegible] Review results: [illegible]

[illegible] the effects of implantation [illegible] establishment of a [illegible]

[illegible] intracapsular [illegible] extraction of [illegible] and anterior chamber lenses. [illegible] will include use of extracapsular technique [illegible] chamber lenses.

[illegible] Approximately ten lenses are implanted [illegible] cystoid macular edema in three patients and prolonged [illegible] in four patients. The technique has been [illegible] point where this procedure appears to be safe.

Detail Summary Sheet

Protocol: 2/82 Status: Terminated

Title: Radioisotope Scanning in the Diagnosis of Bone and Joint Infections

Start Date: Sep 82	Est Completion:
Principal Investigator:	Facility:
[illegible] Landry, Jr., LTC	Tripler Army Medical Center
Dept/Sec:	Associate Investigators:
Dept of Surgery/Orthopedic Svc	
Key Words:	
Bone scanning	
Infections, orthopedic	
Category: [illegible]	Est Recruitment: [illegible]
[illegible]	[illegible] Patients
	Previous Control Protocol:

Objectives: To evaluate the usefulness of radioisotope scanning in the diagnosis of orthopedic infections. Also, to [illegible] radioisotope scans should be employed early in the disease.

Methodology: Orthopedic inpatient files from [illegible] will be reviewed and patients with the diagnoses of septic arthritis, [illegible], and osteomyelitis will be evaluated. X-rays and scans that were performed will be analyzed in an attempt to evaluate the utility of identified by clinical, radiographic, and radioisotope examinations.

Progress: The project is terminated due to the departure of the principal investigator.

Detail Summary Sheet

Date: 5 Jan 87 | Prot No: 1476 | Status: Terminated

Title: Partial Cystectomy followed by Cholecystectomy and Augmentation Cystoplasty with the Gallbladder in Dogs

Start Date: Jun 86	1st Comp Date:
Principal Investigator:	Facility:
Maj George G. Nygatt, MC	Tripler Army Medical Center
Dept/Sec:	Associate Investigators:
Dept of Surgery/Urology	
Key Words:	
Dog; Bladder defects	

Cumulative Cost:	Est Accumulative Costs:
FY87 Costs: $500.	Service Component:

OBJECTIVE: To determine the feasibility of closing bladder defects with free grafts of gallbladder.

TECHNICAL APPROACH: Gallbladders have been used to correct surgical defects in the bones of urinary bladders in eight dogs.

PROGRESS: This project is terminated due to the departure of the principal investigator.

Detail Summary Sheet

Date of Draft: [illegible] Date [illegible]
Title: Compartment Syndrome of the Lower [illegible]

[illegible] Date:
Principal Investigator:
[illegible]
Service:
[illegible]
Facility:
[illegible]
Professional Staff [illegible]

Comprehensive Clinical Evaluative Series
[illegible]

Background: To review compartment syndromes related to [illegible] including anatomy, physiology, tissue pressure determinations, pathophysiological science, treatment, and the clinical approach to [illegible].

Methods: Established an computer [illegible] of compartment syndrome, the dynamics of circuits involved with compartment syndrome, reviewed the anatomy of the lower leg and its compartments, the physiology involved within compartments, various ways of determining tissue pressure measurements, history of the etiological factors involved in compartment syndromes, treatments currently recommended for compartments syndromes, case report, and a clinical approach.

Results: The possibility of closed compartment syndrome should be considered whenever pain or a neuromuscular deficit occurs in an extremity and there are signs of a disturbance in circulation with increased tissue pressure. Tight bandaging is a common cause, and pulsation may be present even when tissue pressure is not occurring. Delay in diagnosis and decompression may lead to irreversible damage, loss of function, and amputation. Fasciotomy is necessary to check the rise in tissue pressure that causes circulation to be delayed.

[illegible] Compartment Syndrome of the Lower [illegible]
[illegible], June 1981.

[illegible]

[illegible]	[illegible]
[illegible] Investigator:	Facility:
[illegible] Center, [illegible]	Tripler Army Medical Center
[illegible]	Associate Investigators:
[illegible]	
[illegible]	
[illegible]	

[illegible] Accumulative Periodic
[illegible] Joint Bone Scans

[illegible] to determine the true nature and etiology of [illegible] [illegible] presented.

[illegible] will be [illegible] to include the measurement of patient [illegible], presence or absence of apprehension test, presence [illegible] and presence or absence of subluxability of [illegible]. Bone scanning will be done using technetium-labeled [illegible]. Abnormalities on x-ray or bone scan will be followed [illegible] intervals. All patients with symptoms lasting three [illegible] following conservative treatment will be scheduled for [illegible] evaluation of the knee joint. Patients will be followed for [illegible] following arthrotomy or surgical treatment if indicated.

FINDINGS. Gathering of clinical data has been completed. We are now in the process of collating the data to permit final conclusions. It appears that while radionuclide scanning is a sensitive indicator of patellar dysfunction, it is not specific enough to be of great value in the routine diagnosis of patellar disorders. However, some subcategories seem to have specific appearance on bone scan and we therefore can envision its use in specific applications. We plan to prepare this data in final form and submit it for publication in the near future.

Initial findings were presented at the Society of Military Orthopedic Surgeons Meeting in November 1979.

[illegible]

[illegible] Upper Extremity Fractures in Children.

[illegible]
Principal Investigator:
[illegible] Kleinker, M.D.
[illegible]
Dept of Surgery/Orthopedics
[illegible]
Fractures, Upper Extremity

[illegible]
Facility:
Tripler Army Medical Center
[illegible]

[illegible] Cumulative [illegible] Periodic
[illegible] Cost Sharing Review [illegible] Interim

[illegible] To assess the results of treatment of upper extremity fractures in children at Tripler Army Medical Center with respect to [illegible], malunion, nonunion, and other complications.

[illegible] Clinical outpatient [illegible] records (both [illegible] available) have been searched and fracture [illegible] the upper extremity in children from birth to 14 years have been [illegible]. [illegible] information has been summarized into categories of [illegible] age, the length of follow-up, the diagnosis, complications occurring, [illegible], and the treatment for the specific injury. Eighteen months total [illegible] cases have been collected. Injuries will be divided [illegible] to those of the phalanges, metacarpals and carpals, distal forearm, [illegible] forearm, elbow, upper arm, shoulder, and clavicle. For each fracture site, the average age, length of follow-up, complications, and treatment will be summarized. Due to the large number of items involved, it is felt that statistical analysis with the aid of computer programming is necessary for full realization of the information available. Attempts will be made to clarify which fractures have the greatest potential for malunion, nonunion, or delayed healing. Also, the individual forms of treatment will be classified as to their adequacy or inadequacy. Precise indications for specific therapy in each group can then be formulated.

[illegible]: Preliminary contact has been made with the computer center and arrangements have been made for data to be collated. Further arrangements have been hampered by ICS of CPT Landry who accomplishes the preliminary contacts. Progress on the project is expected to resume soon.

[illegible]

[illegible] Project No. [illegible] Status: Terminated
Title: [illegible] Cell Antigenicity of Canine Tunica Albuginea

[illegible] Start Date: Aug 76
Principal Investigator:
[illegible] Fonseca, Lt Col, MC
[illegible]
[illegible] Surgery/Urology
[illegible]
[illegible] Maryland

FCI (Component Project)
Facility:
Tripler Army Medical Center
Associate Investigator:
CPT Edward [illegible], MC

[illegible] Cumulative Dollars:
[illegible] FY 1977 $0. Level Support

[illegible] Objective: The objective is to determine the [illegible] tunica albuginea.

[illegible] Approach: Canine tunica albuginea will be [illegible] with skin specimens. The tunica will be [illegible] of tunica albuginea and skin will be sutured orthotopically. The response to each sutured specimen will be judged as to their cellular immune response. The sutured skin specimen will serve as controls. The amount of response to each specimen will be measured and compared to skin controls.

PROGRESS: This project is terminated due to lack of time on the part of the investigators.

[illegible] Jan 8[illegible] Prot No. 1177[illegible] Status: Terminated
Title: Myocardial Oxygen Supply-Demand Ratio: The reliability of clinical approximations in prediction of subendocardial [illegible]

Current Investigators	1st Completed
Principal Investigator:	Facility:
Col Paul L. Snetler, MC	Tripler Army Medical Center
Dept/Sec:	Associate Investigators:
Chief, of Surgery	Gordon H. Bryant
Keywords:	
Subendocardial ischemia	

Cumulative Enrollment	1st Accumulative Periodic
[illegible] for [illegible]	Review Results [illegible]

Objectives: To determine clinically useful hemodynamic factors reflecting myocardial subendocardial ischemia resulting from [illegible]

Methodology: Experimental animals will be prepared [illegible] electromagnetic flow probes to replace [illegible] ventricular electrocardiogram electrodes indicates ischemic changes. Subendocardial viability ratio perturbations by oxygen delivery, arterial oxygen content, cardiac index, and left ventricular stroke work will be correlated with ratio of diastolic coronary blood flow and tension time index to assess the reliability of the hemodynamic factor in warning of impending subendocardial ischemia.

Progress: Production of monitor has been discontinued. The project is therefore terminated.

Detail Summary Sheet

Date: 14 Jan 82 Prot No. 7277 Status: Terminated
TITLE: Teflon Injection Indications

Start Date: Aug 78 Principal Investigator: Col Thomas L. Van Sooy, II Dept/Sec: Dept of Surgery/Otolaryngology Key Words: Teflon injection	Est Comp Date: Indefinite Facility: Brooke Army Medical Center Precedence Level Justification: Will benefit Army Personnel
Cumulative FEDCAST Cost: FY 82	1st Accumulative O&MA Cost: $300.	Periodic Review Results: Terminate

OBJECTIVES: To participate in expanded clinical trials of Ethicon Polytef Paste for Injection for the following clinical indications: the selected treatment of patients with velopharyngeal insufficiency and/or abnormally patent eustacian tubes.

CLINICAL APPROACH: The protocol will follow the clinical study group proposals. Patients will originate in the ENT Clinic. Only patients who have not responded to conventional treatment modalities will be considered. The procedure with its possible risks will be explained to the patient, as well as its investigative nature. If the patient agrees to participate, the case history will be forwarded for consideration to the study group who will furnish the necessary material (Teflon). Patients will require hospitalization for approximately 1-3 days for the surgical procedure which will be done under appropriate anesthesia. Surgery time will be 30 minutes to one hour. The patients will continue to be followed on an outpatient basis for a minimum of [illegible] days as required by the protocol.

PROGRESS: The project is terminated as Ethicon Inc. [illegible] no longer produces Polytef Paste for this use.

[illegible] Project [illegible] Protocol [illegible] Status: Ongoing
Title: Several (sublabial) rhinoplasty approach [illegible] of the middle third of [illegible]

[illegible] Name and [illegible] Principal Clinical Investigator: [illegible] Department: [illegible]	[illegible] Participating Facility: [illegible] Associate Investigators: [illegible]
Accrual to Date: [illegible] Total Projected Accrual: [illegible]	Periods: [illegible] Review Result: [illegible]

Objectives: To present an instructional course on the technique and application of the columellar rhinoplasty approach and to record, [illegible] instructional unit on the procedure.

Background/Rationale: The columellar rhinoplasty approach is a relatively [illegible] surgical approach to the nasal infrastructure that allows many reconstructive procedures to be performed under direct vision. The project was undertaken to explore the indications for its use as well as provide training or information on the performance of the procedure.

Progress: The technique has been used in selective cases for approximately 3 years by the investigators. A course of instruction on the procedure illustrated by double slide projection and 3/4" video tape has been developed and presented by invitation on several occasions. A collaborative study with the Neurosurgery service is underway comparing this approach with the sublabial approach for transseptal transsphenoidal pituitary surgery. A teaching video tape is in development. An invitation has been received to continue presenting the instructional course in its present format at the American Academy of Otolaryngology-Head and Neck Surgery annual meeting, instruction course program for the next [illegible] years.

Presented at the American Academy of Otolaryngology-Head and Neck Surgery, New Orleans, Louisiana, Sept 1981.

[illegible] Project [illegible] Category [illegible]
II.F.1.b.(1) Ureterogastric Urinary Conduit

[illegible]
Principal Investigator
[illegible]
[illegible]
[illegible] of Surgery [illegible]
[illegible]
Ureterogastric Urinary Conduit

[illegible]
Facility
[illegible]
[illegible]
[illegible]

Cumulative FY87/ASL | 1st Accumulative SMA Cost: $2800. | Periodic Review [illegible]

OBJECTIVE: To investigate the feasibility of using gastric stoma as an alternative conduit for urinary diversion and as a substitute for the urinary bladder. To compare the advantages/disadvantages of this conduit to the present methods of urinary diversion.

METHODS AND RESULTS: The technical approach of this project is through a [illegible] midline laparotomy incision. A gastric pouch is created by the greater curvature of the stomach with vascular supply from the gastroepiploic artery. The ureter is then diverted into the gastric pouch and the gastric pouch is brought to the skin as a cutaneous ostomy. Preoperative and postoperative renal function [illegible] condition, electrolytes and gastrin are assessed.

[illegible] Nine dogs have undergone ureterogastric urinary [illegible] operation. There were two deaths, one resulting from [illegible] and one from bilateral hydronephrosis with renal failure. Two of the dogs developed unilateral ureterogastric anastomotic strictures, one of these resulting from stenting. Four dogs had [illegible] We plan to add two additional dogs to the study.

Detail Summary Sheet

Title: Strain differences of staphylococcus aureus by gas liquid chromatographic analysis

Principal Investigator: Steven F. Oshi, PSC	Facility: Triple Army Medical Center
Associate Investigators: CPT Carroll L. Jetson, MSC	
Keywords: Staphylococcus aureus	
Cooperative Research Effort:	Est Accumulative OMA Cost: $1500.
	Periodic Review Results: Continue

OBJECTIVE: To examine the feasibility of determining strain differences of Staphylococcus aureus by analysis of gas liquid chromatography (GLC) fatty acid profiles. If strain differences can be demonstrated, epidemiologic analysis can be simplified, and rapid laboratory analysis can be made without resorting to time-consuming phage typing.

METHODICAL APPROACH: Strains of S. aureus will be collected and identified to species by the Microbiology Section, Department of Pathology, WRAMC. Organisms will be prepared for gas chromatographic analysis using a modification of the method of Oshashi. Briefly, whole cells will be prepared for GLC analysis using tetramethylammonium hydroxide by a very simple procedure requiring less than two hours for the preparation of a dozen samples. The organisms will grow on several media formulations to determine which media will enhance lipid accumulation by the strains being examined. Gas chromatographic data will be subjected to pattern analysis and strain differences will be defined in terms of observed deviations.

PROGRESS: Because of higher priority being given other work, further progress in the laboratory has not been accomplished. However, a method by which oxidation of materials can be prevented has been devised, and manipulation of cell lipid composition is planned.

[illegible] Protocol [illegible] Status: [illegible]
Title: Studies on the Bacteriology of Acid Fast Isolates Recovered from Lepromatous Leprosy Patients

Start Date: Nov 80	Est Comp Date:
Principal Investigator: LTC David F. Ohashi, MSC	Facility: Tripler Army Medical Center
Dept/Sec: Health Services Command Key Words: Leprosy	Associate Investigators:
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $500.
	Periodic Review Results:

Objectives: To study the colonial dissociation and selected bacterial characteristics of bacteria claimed to be the etiologic agent of leprosy.

Technical Approach: M. leprae, the etiologic agent of human leprosy, has not yet been accepted as growing on cell-free media. Two novel strains were recovered from the tissues of lepromatous leprosy patients using a new hyaluronic acid based medium by Dr. Olaf J. Kirchheimer, an internationally recognized authority on leprosy. [illegible] were demonstrated by him to be immunologically reactive in absorbed sera, specific for M. leprae. Approximately 60 standardized determinative tests selected from international collaborative studies on the taxonomy of the mycobacteria were performed on these two isolates plus a selected number of reference strains from the Trudeau collection. These two isolates were also tested in a seroagglutination procedure which has been developed to identify type-specific antigens of the Mycobacterium avium-intracellulare-scrofulaceum complex (MAIS). Careful examination of the colony morphology on translucent agar indicated that both colonies have smooth and rough forms and that either smooth or rough forms will spontaneously give rise to both forms.

Progress: The two strains have been identified as M. intracellulare closely related to type 7 and M. scrofulaceum type 41.

M. intracellulare and M. scrofulaceum belong to a group of mycobacteria that are usually pigmented. If one reviews the literature for the past 50 years, one finds that many famous scientists have claimed to have isolated M. leprae. Because standardized, determinative tests have become available for the genus mycobacterium in the past 15 years, it is almost impossible to precisely identify other isolates claimed to be

[illegible]

[illegible] the literature. [illegible]

[illegible] M. leprae [illegible] Corynebacteria frequently are present in the tissues of Hansen's disease patients. M. leprae lacks many commonly found enzymes which [illegible] mycobacteria have.

[illegible] isolates used in this study have been better characterized than any previous mycobacteria claimed to be M. leprae. [illegible] of the fact that both isolates are immunologically reactive, [illegible] they possess a [illegible] mycoside since this is the immunologically active [illegible] in the agglutination procedure. [illegible] mycosides have been characterized by a group in Denver, Colorado and the [illegible] the basic mycoside structure has been determined, it has been [illegible] logically that this basic structure is also present in M. leprae [illegible] it forms the famous electron transparent zone around the cell of M. leprae which probably defeats phagolysosomal activity and allows M. leprae its intracellular existence within macrophages.

In summary, the two Skinsness isolates are probably very similar to many other mycobacteria that have been claimed by other workers to be M. leprae. Peculiarly, they share a unique structure which [illegible] exists on M. leprae. On the other hand, both Skinsness [illegible] will grow on a mineral salts medium while M. leprae does not. Nevertheless, it is concluded that the Skinsness organisms, as well as other mycobacteria isolated from the tissues of Hansen's disease patients, [illegible] uniquely related to M. leprae. To account for this relationship, it is hypothesized that some means of genetic transfer may occur in which M. leprae acquires genetic information from other bacterial cells. The genetic transfer could come from other acid fast mycobacteria or, more probably, the Corynebacteria present in the tissues that are obtained at the time of cultivation.

A manuscript is in preparation for presentation to the American Society of Microbiology, and a separate manuscript is in preparation for inclusion in dissertation.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